sedimentation basin averaging 0.20 log. Removal of aerobic spores, total particle counts, and turbidity all correlated well with removal of *Cryptosporidium* by sedimentation.

States *et al.* (1997) monitored *Cryptosporidium* removal at the Pittsburgh Drinking Water Treatment Plant (65–70 million gallons per day (MGD)). The clarification process included ferric chloride coagulation, flocculation, and settling in both a small primary basin and a 120 MG secondary sedimentation basin. Geometric mean *Cryptosporidium* levels in the raw and settled water were 31 and 12 oocysts/100 L, respectively, indicating a mean reduction of 0.41 log.

Edzwald and Kelly (1998) conducted a bench-scale study to determine the optimal coagulation conditions with different coagulants for removing *Cryptosporidium* oocysts from spiked raw waters. Under optimal coagulation conditions, the authors observed oocysts reductions through sedimentation ranging from 0.8 to 1.2 log.

Payment and Franco (1993) measured *Cryptosporidium* and other microorganisms in raw, settled, and filtered water samples from drinking water treatment plants in the Montreal area. The geometric mean of raw and settled water *Cryptosporidium* levels in one plant were 742 and 0.12 oocysts/100 L, respectively, suggesting a mean removal of 3.8 log. In a second plant, mean removal by sedimentation was reported as 0.7 log, with raw and settled water *Cryptosporidium* levels reported as <2 and <0.2 oocysts/L, respectively.

Kelley *et al.* (1995) monitored *Cryptosporidium* levels in the raw, settled, and filtered water of two water treatment plants (designated site A and B). Both plants included two-stage sedimentation. At site A, mean raw and settled water *Cryptosporidium* levels were 60 and 9.5 oocysts/100 L, respectively, suggesting a mean removal of 0.8 log by sedimentation. At site B, mean raw and settled water *Cryptosporidium* levels were 53 and 16 oocysts/100 L, respectively, for an average removal by sedimentation of 0.5 log. Well water was intermittently blended in the second stage of sedimentation at site B, which may have reduced settled and filtered water pathogen levels.

Patania *et al.* (1995) evaluated removal of *Cryptosporidium* in four pilot scale plants. Three of these were conventional and one used in-line filtration (rapid mix followed by filtration). *Cryptosporidium* removal was generally 1.4 to 1.8 log higher in the process trains with sedimentation compared to in-line filtration. While the effectiveness of sedimentation for organism removal varied widely under the conditions tested, the median removal of *Cryptosporidium* by sedimentation was approximately 2.0 log.

ii. Data supplied by utilities on the removal of spores by presedimentation. Data on the removal of *Cryptosporidium* and spores (Bacillus subtilis and total aerobic spores) during operation of full-scale presedimentation basins were collected independently and reported by three utilities: St. Louis, MO, Kansas City, MO, and Cincinnati, OH. *Cryptosporidium* oocysts were not detected in raw water at these locations at levels sufficient to calculate log removals of oocysts directly. However, aerobic spores were present in the raw water of these utilities at high enough concentrations to measure log removals through presedimentation as a surrogate for *Cryptosporidium* removal. As noted earlier, data from Dugan *et al.* (2001) demonstrate a correlation between removal of aerobic spores and *Cryptosporidium* through sedimentation under optimal coagulation conditions. A summary of the spore removal data supplied by the these utilities is shown in Table IV–11.

TABLE IV–11.—MEAN SPORE REMOVAL FOR FULL-SCALE PRESEDIMENTATION BASINS REPORTED BY THREE UTILITIES

Reporting utility	Mean spore removal
St. Louis Water Division.	1.1 log (B. subtilis).
Kansas City Water Services Department.	0.8 log (B. subtilis) (with coagulant).
	0.46 log (B. subtilis) (without coagulant).
Cincinnati Water Works.	0.6 log (total aerobic spores).

The St. Louis Water Division operates four presedimentation basins at one facility. Coagulant addition prior to presedimentation includes polymer and occasional dosages of ferric sulfate. Bacillus subtilis spore samples were collected from June 1998 to September 2000. Reported mean spore concentrations in the raw water and following presedimentation were 108,326 and 8,132 cfu/100 mL, respectively, showing an average removal of 1.1 log by presedimentation.

The Kansas City Water Services Department collected Bacillus subtilis spore samples from January to November 2000 from locations before and after one of the facility's six presedimentation basins. Sludge generated by the primary clarifier of a softening process was recycled to the head of the presedimentation basins during the entire study period. In addition, coagulant (polymer and/or ferric sulfate) was added prior to presedimentation when raw water turbidity was higher. During periods when coagulant was added, mean spore levels before and after presedimentation were 102,292 and 13,154 cfu/100 mL, respectively, demonstrating a mean removal of 0.9 log. When no ferric sulfate or polymer was used, mean presedimentation influent and effluent spore levels were 13,296 and 4,609 cfu/100 mL, respectively, for an average reduction of 0.46 log.

The Cincinnati Water Works operates a treatment plant using lamella plate settlers for presedimentation. Lamella plate settlers are inclined plates added to a sedimentation basin to significantly increase the surface area available for particle settling. Coagulant (alum and polymer) is added to the raw water prior to presedimentation. Total aerobic spore samples were collected from January 1998 through December 2000. The mean concentration of spores decreased from 20,494 cfu/100 mL in the raw water to 4,693 cfu/100 mL in the presedimentation effluent, indicating a mean spore removal of 0.64 log.

In conclusion, literature studies clearly establish that sedimentation basins are capable of achieving greater than 0.5 log reduction in *Cryptosporidium* levels. Further, the data supplied by utilities on reduction in aerobic spore counts across full scale presedimentation basins demonstrate that presedimentation can achieve mean reductions of greater than 0.5 log under routine operating conditions and over an extended time period. Thus, these data suggest that a 0.5 log presumptive credit for *Cryptosporidium* removal by presedimentation is appropriate under certain conditions.

With respect to the conditions under which the 0.5 log presumptive credit for presedimentation is appropriate, the data do not demonstrate that this level of removal can be achieved consistently without a coagulant. In addition, available data do not establish aerobic spores as an effective indicator of *Cryptosporidium* removal in the absence of a coagulant. Thus, supporting data are consistent with a requirement that systems apply a coagulant to be eligible for the presumptive 0.5 log presedimentation credit. Moreover, such a requirement is consistent with the Agreement in Principle, which recommends 0.5 log credit for presedimentation basins with a coagulant.

EPA also has concluded that presedimentation basins need to be operated continuously and treat 100% of the plant flow in order to reasonably ensure that the process will reduce influent *Cryptosporidium* levels by at least 0.5 log over the course of a full year. The Agency recognizes that, depending on influent water quality, some systems may determine it is more prudent to operate presedimentation basins intermittently in response to fluctuating turbidity levels. By proposing these conditions for the presumptive presedimentation credit, EPA is not recommending against intermittent operation of presedimentation basins. Rather, EPA is attempting to identify the conditions under which a 0.5 log presumptive credit for presedimentation is warranted.

In response to the SAB panel recommendation that performance criteria other than overflow rate be included if credit is to be given for presedimentation, EPA analyzed the relationship between removal of spores and reduction in turbidity through presedimentation for the three utilities that supplied these data. Results of this analysis are summarized in Table IV–12, which shows the relationship between monthly mean turbidity reduction and the percent of months when mean spore removal was at least 0.5 log.

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Table IV-12.-- Relationship Between Mean Turbidity Reduction and the Percent of Months When Mean Spore Removal Was at Least 0.5 Log

Log Reduction in Turbidity (monthly mean)	Percent of Months with at least 0.5 Log Mean Reduction in Spores
>= 0.1	64%
>= 0.2	68%
>= 0.3	73%
>= 0.4	78%
>= 0.5	89%
>= 0.6	91%
>= 0.7	90%
>= 0.8	89%
>= 0.9	95%
>= 1.0	96%

Source: Data from Cincinnati Water Works, Kansas City Water Services Department, and St. Louis Water Division

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Within the available data set, achieving a mean turbidity reduction of at least 0.5 log appears to provide approximately a 90% assurance that average spore removal will be 0.5 log or greater. The underlying data are shown graphically in Figure IV–4. Based on this information, EPA has concluded that it is appropriate to require 0.5 log turbidity reduction, determined as a monthly mean of daily turbidity readings, as an operating condition for the 0.5 log presumptive *Cryptosporidium* treatment credit for presedimentation. Further, EPA is proposing that systems must meet the 0.5 log turbidity reduction requirement in at least 11 of the 12 previous months on an ongoing basis to remain eligible for the presedimentation credit.

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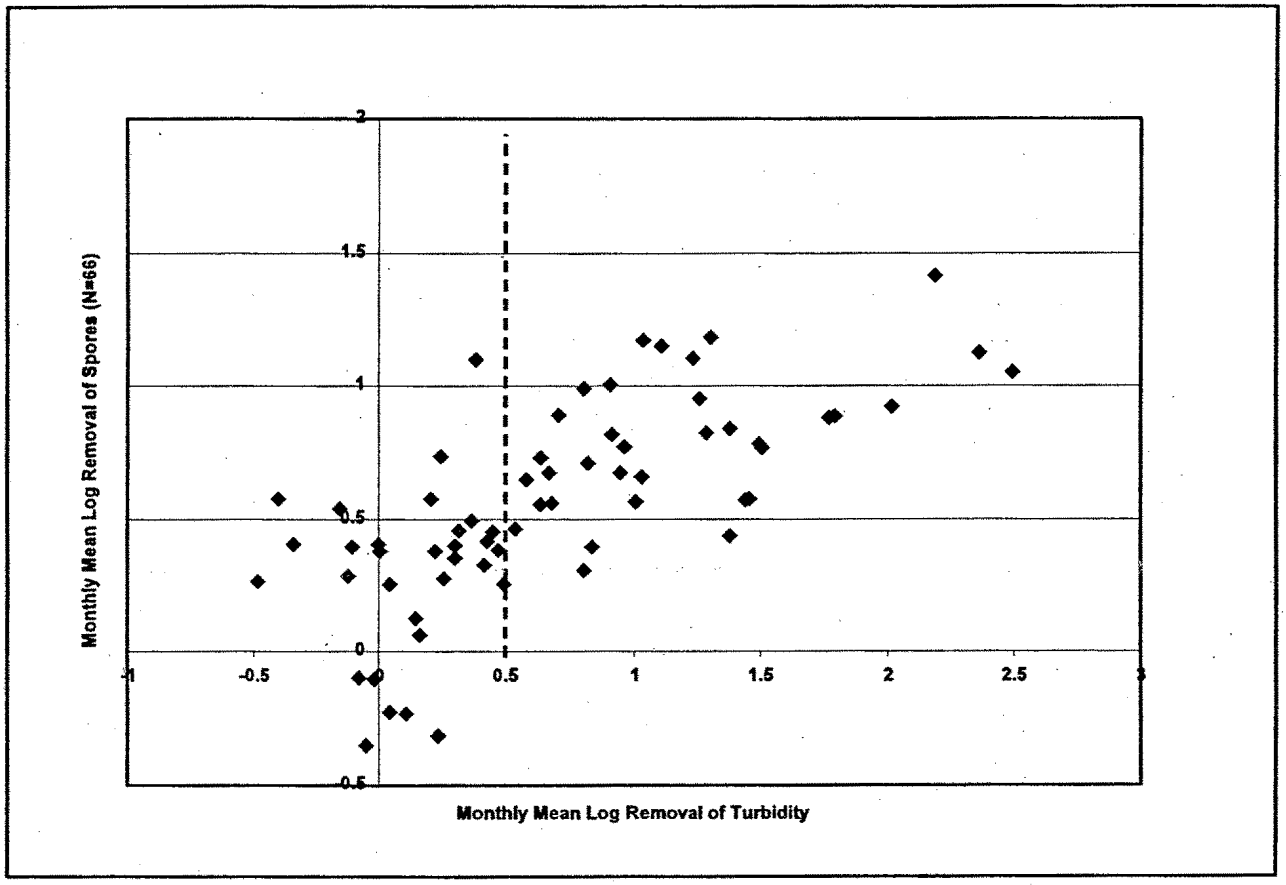

Figure IV-4.-- Monthly Mean Log Removal of Spores from Presedimentation vs. Monthly Mean Turbidity Log Reduction

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c. Request for comment. EPA requests comment on the proposed criteria for awarding credit to presedimentation. EPA would particularly appreciate comment on the following issues:

- Whether the information cited in this proposal supports the proposed credit for presedimentation and the operating conditions under which the credit will be awarded;
- Additional information that either supports or suggest modifications to the proposed performance criteria and presumptive credit;
- Today's proposal requires systems using presedimentation to sample after the presedimentation basin, and these systems are not eligible to receive additional presumptive *Cryptosporidium* removal credit for presedimentation. However, systems are also required to collect samples prior to chemical treatment, and EPA recognizes that some plants provide chemical treatment to water prior to, or during, presedimentation. EPA requests comment on how this situation should be handled under the LT2ESWTR.
- Whether and under what conditions factors like low turbidity raw water, infrequent sludge removal, and wind would make compliance with the 0.5 log turbidity removal requirement infeasible.

6. Bank Filtration

a. *What is EPA proposing today?* EPA is proposing to award additional *Cryptosporidium* treatment credit (0.5 or 1.0 log) for systems that implement bank filtration as a pre-treatment technique if it meets the design criteria specified in this section. To be eligible for credit as a pre-treatment technique, bank filtration collection devices must meet the following criteria:

- Wells are drilled in an unconsolidated, predominantly sandy aquifer, as determined by grain-size analysis of recovered core material—the recovered core must contain greater than 10% fine-grained material (grains less than 1.0 mm diameter) in at least 90% of its length;
- Wells are located at least 25 feet (in any direction) from the surface water source to be eligible for 0.5 log credit; wells located at least 50 feet from the source surface water are eligible for 1.0 log credit;
- The wellhead must be continuously monitored for turbidity to ensure that no system failure is occurring. If the monthly average of daily maximum turbidity values exceeds 1 NTU then the system must report this finding to the State. The system must also conduct an assessment to determine the cause of the high turbidity levels in the well and consult with the State regarding whether previously allowed credit is still appropriate.

Systems using existing bank filtration as pretreatment to a filtration plant at the time the systems are required to conduct *Cryptosporidium* monitoring, as described in section IV.A, must sample the well effluent for the purpose of determining bin classification. Where bin classification is based on monitoring the well effluent, systems are not eligible to receive additional credit for

bank filtration. In these cases, the performance of the bank filtration process in reducing *Cryptosporidium* levels will be reflected in the monitoring results and bin classification.

Systems using bank filtered water without additional filtration typically must collect source water samples in the surface water (*i.e.*, prior to bank filtration) to determine bin classification. This applies to systems using bank filtration to meet the *Cryptosporidium* removal requirements of the IESWTR or LT1ESWTR under the provisions for alternative filtration demonstration in 40 CFR 141.173(b) or 141.552(a). Note that the proposed bank filtration criteria for *Cryptosporidium* removal credit under the LT2ESWTR do not apply to existing State actions to provide alternative filtration *Cryptosporidium* removal credit for IESWTR or LT1ESWTR compliance.

In the case of systems that use GWUDI sources without additional filtration and that meet all the criteria for avoiding filtration in 40 CFR 141.71, samples must be collected from the ground water (*e.g.*, the well). Further, such systems must comply with the requirements of the LT2ESWTR that apply to unfiltered systems, as described in section IV.B.

b. *How was this proposal developed?* This section describes the bank filtration treatment process, provides more detail on the aquifer types and ground water collection devices that are eligible for bank filtration credit, and describes the data supporting the proposed requirements.

Bank filtration is a water treatment process that makes use of surface water that has naturally infiltrated into ground water via the river bed or bank(s) and is recovered via a pumping well. Stream-bed infiltration is typically enhanced by the pumping action of near-stream wells (*e.g.*, water supply, irrigation). Bank filtrate is water drawn into a pumping well from a nearby surface water source which has traveled through the subsurface, either vertically, horizontally or both, mixing to some degree with other ground water. Through bank filtration, microorganisms and other particles are removed by contact with the aquifer materials.

The bank filtration removal process performs most efficiently when the aquifer is comprised of granular materials with open pore-space for water flow around the grains. In these granular porous aquifers, the flow path is meandering, thereby providing ample opportunity for the organism to come into contact with and attach to a grain surface. Although detachment can occur, it typically occurs at a very slow rate so that organisms remain attached to a grain for long periods. When ground water travel times from source water to well are long or when little or no detachment occurs, most organisms will become inactivated before they can enter a well. Thus, bank filtration relies on removal, but also, in some cases, on inactivation to protect wells from pathogen contamination.

Only Wells Located in Unconsolidated, Predominantly Sandy Aquifers Are Eligible

Only granular aquifers are eligible for bank filtration credit. Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles and minor cement. The aquifer material is required to be unconsolidated, with subsurface samples friable upon touch. Uncemented granular aquifers are typically formed by alluvial or glacial processes. Such aquifers are usually identified on a detailed geologic map (*e.g.*, labeled as Quaternary alluvium).

Under today's proposal, a system seeking *Cryptosporidium* removal credit must characterize the aquifer at the well site to determine aquifer properties. At a minimum, the aquifer characterization must include the collection of relatively undisturbed, continuous, core samples from the surface to a depth equal to the bottom of the well screen. The proposed site must have substantial core recovery during drilling operations; specifically, the recovered core length must be at least 90% of the total projected depth to the well screen.

Samples of the recovered core must be submitted to a laboratory for sieve analysis to determine grain size distribution over the entire recovered core length. Each sieve sample must be acquired at regular intervals over the length of the recovered core, with one sample representing a composite of each two feet of recovered core. A two-foot sampling interval reflects the necessity to sample the core frequently without imposing an undue burden. Because it is anticipated that wells will range from 50 to 100 foot in depth, a two-foot sampling interval will result in about 25 to 50 samples for analysis. Each sampled interval must be examined to determine if more than ten percent of the grains in that interval are less than 1.0 mm in diameter (#18 sieve size). In the U.S. Department of Agriculture soil classification system, the #18 sieve separates very coarse sands from coarse sands. The length of core (based on the samples from two-foot intervals) with more than ten percent of the grains less than 1.0 mm in diameter must be summed to determine the overall core length with sufficient fine-grained material so as to provide adequate removal. An aquifer is eligible for removal credit if at least 90% of the sampled core length contains sufficient fine-grained material as defined in this section.

Cryptosporidium oocysts have a natural affinity for attaching to fine-grained material. A study of oocyst removal in sand columns shows greater oocyst removal in finer-grained sands than in coarser-grained sands (Harter *et al.* 2000). The core sampling procedure described in this section is designed to measure the proportion of fine-grained sands (grains less than 1.0 mm in diameter) so as to ensure that a potential bank filtration site is capable of retarding transport (or removing) oocysts during ground water flow from the source surface water to the water supply well. The value of 1.0 mm for the bounding size of the sand grains was determined based on calculations performed by Harter using data from Harter *et al.* (2000). Harter showed that, for ground water velocities typical of a bank filtration site (1.5 to 15 m/day), a typical bank filtration site composed of grains with a diameter of 1.0 mm would achieve at least 1.0 log removal over a 50 foot transport distance. Larger-sized grains would achieve less removal, all other factors being equal.

Alluvial and glacial aquifers are complex mixtures of sand, gravel and other sized particles. Particles of similar size are often grouped together in the subsurface, due to sorting by flowing water that carries and then deposits the particles. Where there exists significant thickness of coarse-grained particles, such as gravels, with few finer materials, there is limited opportunity for oocyst removal. When the total gravel thickness, as measured in a core, exceeds 10%, it is more likely (based on analysis of ground water flow within mixtures containing differing-sized grains) that the gravel-rich intervals are interconnected. Interconnected gravel can form a continuous, preferential flow path from the source surface water to the water supply well. Where such preferential flow paths exist, a preponderance of the total ground water flow occurs within the preferential flow path, ground water velocity is higher, and natural filtration is minimal. A proposed bank filtration site is acceptable if at least 90% of the core length contains grains with sufficient fine-grained material (diameter less than 1.0 mm); that is, it is acceptable if the core contains less than 10% gravel-rich intervals.

Aquifer materials with significant fracturing are capable of transmitting

ground water at high velocity in a direct flow path with little time or opportunity for die-off or removal of microbial pathogens. Consolidated aquifers, fractured bedrock, and karst limestone are aquifers in which surface water may enter into a pumping well by flow along a fracture, a solution-enhanced fracture conduit, or other preferential pathway. Microbial pathogens found in surface water are more likely to be transported to a well via these direct or preferential pathways. *Cryptosporidium* outbreaks have been associated with consolidated aquifers, such as a fractured chalk aquifer (Willocks *et al.* 1998) or a karst limestone (solution-enhanced fractured) aquifer (Bergmire-Sweat *et al.* 1999). These outbreaks show that the oocyst removal performance of consolidated aquifers is undermined by preferential water flow and oocyst transport through rock fractures or through rock dissolution zones. Wells located in these aquifers are not eligible for bank filtration credit because the flow paths are direct and the average ground water velocity is high, so that little inactivation or removal would be expected. Therefore, only unconsolidated aquifer are eligible for bank filtration oocyst removal credit.

A number of devices are used for the collection of ground water including horizontal and vertical wells, spring boxes, and infiltration galleries. Among these, only horizontal and vertical wells are eligible for log removal credit. The following discussion presents characteristics of ground water collection devices and the basis for this proposed requirement.

Horizontal wells are designed to capture large volumes of surface water recharge. They typically are constructed by the excavation of a central vertical caisson with laterals that extend horizontally from the caisson bottom in all directions or only under the riverbed. Horizontal wells are usually shallower than vertical wells because of the construction expense. Ground water flow to a horizontal well that extends under surface water is predominantly downward. In contrast, ground water flow to a vertical well adjacent to surface water may be predominantly in the horizontal direction. Surface water may have a short ground water flow path to a horizontal well if the well extends out beyond the bank.

Hancock *et al.* (1998) analyzed samples from eleven horizontal wells and found *Cryptosporidium*, Giardia or both in samples from five of those wells. These data suggest that some horizontal wells may not be capable of achieving effective *Cryptosporidium* removal by bank filtration. Insufficient data are currently available to suggest that horizontal well distances from surface water should be greater than distances established for vertical wells. Two ongoing studies in Wyoming (Clancy Environmental Consultants 2002) and Nebraska (Rice 2002) are collecting data at horizontal well sites.

A spring box is located at the ground surface and is designed to contain spring outflow and protect it from surface contamination until the water is utilized. Spring boxes are typically located where natural processes have enhanced and focused ground water discharge into a smaller area and at a faster volumetric flow rate than elsewhere (*i.e.*, a spring). Often, localized fracturing or solution enhanced channels are the cause of the focused discharge to the spring orifice. Fractures and solution channels have significant potential to transport microbial contaminants so that natural filtration may be poor. Thus, spring boxes are not proposed to be eligible for bank filtration credit.

Cryptosporidium monitoring results (Hancock *et al.* 1998) and outbreaks are used to evaluate ground water collection devices. Hancock *et al.* sampled thirty five springs for *Cryptosporidium* oocysts and Giardia cysts. Most springs were used as drinking water sources and sampling was conducted to determine if the spring should be considered as a GWUDI source. *Cryptosporidium* oocysts were found in seven springs; Giardia cysts were found in five springs; and either oocysts or cysts were found in nine springs (26%). A waterborne cryptosporidiosis outbreak in Medford, Oregon (Craun *et al.* 1998) is associated with a spring water supply collection device. Also, a more recent, smaller outbreak of giardiasis in an Oregon campground is associated with a PWS using a spring. The high percentage of springs contaminated with pathogenic protozoan, the association with recent outbreaks, and an apparent lack of bank filtration capability indicate that spring boxes must not be eligible for bank filtration credit.

An infiltration gallery (or filter crib) is typically a slotted pipe installed horizontally into a trench and backfilled with granular material. The gallery is designed to collect water infiltrating from the surface or to intercept ground water flowing naturally toward the surface water (Symons *et al.* 2000). In some treatment plants, surface water is transported to a point above an infiltration gallery and then allowed to infiltrate. The infiltration rate may be manipulated by varying the properties of the backfill or the nature of the soil-water interface. Because the filtration properties of the material overlying an infiltration gallery may be designed or purposefully altered to optimize oocyst removal or for other reasons, this engineered system is not bank filtration, which relies solely on the natural properties of the system.

A 1992 cryptosporidiosis outbreak in Talent, Oregon was associated with poor performance of an infiltration gallery underneath Bear Creek (Leland *et al.* 1993). In this case, the ground water-surface water interface and the engineered materials beneath did not sufficiently reduce the high oocyst concentration present in the source water. The association of an infiltration gallery with an outbreak, the design that relies on engineered materials rather than the filtration properties of natural filtration media, and the shallow depth of constructed infiltration galleries, such that they typically are not located greater than 25 feet from the surface and surface water recharge, all indicate that infiltration galleries must not be eligible for bank filtration credit.

EPA notes that under the demonstration of performance credit described in section IV.C.17, States may consider awarding *Cryptosporidium* removal credit to infiltration galleries where the State determines, based on site-specific testing with a State-approved protocol, that such credit is appropriate (*i.e.*, that the process reliably achieves a specified level of *Cryptosporidium* removal on a continuing basis).

Wells Located 25 Feet From the Surface Water Source Are Eligible for 0.5 Log Credit; Wells Located 50 Feet From the Surface Water Source Are Eligible for 1.0 Log Credit

A vertical or horizontal well located adjacent to a surface water body is eligible for bank filtration credit if there is sufficient ground water flow path length to effectively remove oocysts. For vertical wells, the wellhead must be located at least 25 horizontal feet from the surface water body for 0.5 log *Cryptosporidium* removal credit and at least 50 horizontal feet from the surface water body for 1.0 log *Cryptosporidium* removal credit. For horizontal wells, the laterals must be located at least 25 feet distant from the normal-flow surface water riverbed for 0.5 log *Cryptosporidium* removal credit and at least 50 feet distant from the normal-flow surface water riverbed for 1.0 log *Cryptosporidium* removal credit.

The ground water flow path to a vertical well is the measured distance from the edge of the surface water body, under high flow conditions (determined by the mapped extent of the 100 year

floodplain elevation boundary or floodway, as defined in Federal Emergency Management Agency (FEMA) flood hazard maps), to the wellhead. The ground water flow path to a horizontal well is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral.

The floodway is defined by FEMA as the area of the flood plain where the water is likely to be deepest and fastest. The floodway is shown on FEMA digital maps (known as Q3 flood data maps), which are available for 11,990 communities representing 1,293 counties in the United States. Systems may identify the distance to surface water using either the 100 year return period flood elevation boundary or by determining the floodway boundary using methods similar to those used in preparing FEMA flood hazard maps. The 100 year return period flood elevation boundary is expected to be wider than the floodway but that difference may vary depending on local conditions. Approximately 19,200 communities in the United States have flood hazard maps that show the 100 year return period flood elevation boundary. If local FEMA floodway hazard maps are unavailable or do not show the 100 year flood elevation boundary, then the utility must determine either the floodway or 100 year flood elevation boundary.

The separation distance proposed for *Cryptosporidium* removal credit is based, in part, on measured data for the removal of oocyst surrogate biota in full-scale field studies. A variety of surrogate and indicator organisms were analyzed in each study evaluated for today's proposal. However, only two non-pathogenic organisms, anaerobic clostridia spores and aerobic endospores, are resistant to inactivation in the subsurface, approximately similar in size and shape to oocysts, and sufficiently ubiquitous in both surface water and ground water so that log removal can be calculated during passage across the surface water—ground water interface and during transport within the aquifer.

Anaerobic spores are typically estimated at about 0.3–0.4 μm in diameter as compared with 4–6 μm for oocysts. Aerobic spores, such as endospores of the bacterium Bacillus subtilis, are slightly larger than anaerobic spores, typically $0.5 \times 1.0 \times 2.0$ μm in diameter (Rice *et al.* 1996). Experiments conducted by injecting Bacillus subtilis spores into a gravel aquifer show that they can be very mobile in the subsurface environment (Pang *et al.* 1998). As presented in the following discussion, available data indicate similar removal of both aerobic and anaerobic spores, either during passage across the surface water—ground water interface or during ground water flow. These data suggest that anaerobic spores, like aerobic spores, may be suitable surrogate measures of *Cryptosporidium* removal by bank filtration.

Available data establish that during bank filtration, significant removal of anaerobic and aerobic spores can occur during passage across the surface water-ground water interface, with lesser removal occurring during ground water transport within the aquifer away from that interface. The ground water-surface water interface is typically comprised of finer grained material that lines the bottom of the riverbed. Typically, the thickness of the interface is small, typically a few inches to a foot. The proposed design criteria of 25 and 50 feet for 0.5 and 1.0 log *Cryptosporidium* removal credit, respectively, are based on EPA's analysis of pathogen and surrogate monitoring data from bank filtration sites. Most of these data are from studies of aquifers developed in Dutch North Sea margin sand dune fields and, therefore, represent optimal removal conditions consistent with a homogenous, well sorted (by wind), uniform sand filter.

Medema *et al.* (2000) measured 3.3 log removal of anaerobic spores during transport over a 13 m distance from the Meuse River into adjacent ground water. Arora *et al.* (2000) measured greater than 2.0 log removal of anaerobic spores during transport from the Wabash River to a horizontal collector well. Havelaar *et al.* (1995) measured 3.1 log removal of anaerobic spores during transport over a 30 m distance from the Rhine River to a well and 3.6 log removal over a 25 m distance from the Meuse River to a well. Schijven *et al.* (1998) measured 1.9 log removal of anaerobic spores over a 2 m distance from a canal to a monitoring well. Using aerobic spores, Wang *et al.* (2001) measured 1.8 log removal over a 2 foot distance from the Ohio river to a monitoring well beneath the river.

During transport solely within shallow ground water (*i.e.*, not including removal across the surface water-ground water interface), Medema *et al.* (2000) measured approximately 0.6 log removal of anaerobic spores over a distance of 39 feet. Using aerobic spores, Wang *et al.* (2001) measured 1.0 log removal of aerobic spores over a 48 foot distance from a monitoring well beneath a river to a horizontal well lateral.

At distances relatively far from an injection well in a deep, anaerobic aquifer, thereby minimizing the effects of injection, Schijven *et al.* measured negligible removal of anaerobic spores over a 30 m distance. However, few bank filtration systems occur in deeper, anaerobic ground water so these data may not apply to a typical bank filtration system in the United States.

These data demonstrate that during normal and low surface water elevations, the surface water-ground water interface performs effectively to remove microbial contamination. However, there will typically be high water elevation periods during the year, especially on uncontrolled rivers, that alter the nature and performance of the interface due to flood scour, typically for short periods. During these periods, lower removals would be expected to occur.

Averaging *Cryptosporidium* oocyst removal over the period of a year requires consideration of both high and low removal periods. During most of the year, high log removal rates would be expected to predominate (*e.g.*, 3.3 log removal over 42 feet) due to the removal achieved during passage across the surface water-ground water interface. During short periods of flooding, substantially lower removal rates may occur (*e.g.*, 0.5 log removal over 39 feet) due to scouring of the riverbed and removal of the protective, fine-grained material. By considering all time intervals with differing removal rates over the period of a year, EPA is proposing that 0.5 log removal over 25 feet (8 m) and 1.0 log removal over 50 feet (16 m) are reasonable estimates of the average performance of a bank filtration system over a year. This proposal is generally supported by colloidal filtration theory modeling results using data characteristic of the aquifers in Louisville and Cincinnati and column studies of oocyst transport in sand (Harter *et al.* 2000).

Wells must be continuously monitored for turbidity

Under the Surface Water Treatment Rule (40 CFR 141.73(b)(1)) the turbidity level of slow sand filtered water must be 1 NTU or less in 95% of the measurements taken each month. Turbidity sampling is required once every four hours, but may be reduced to once per day under certain conditions. Although slow sand filtration is not bank filtration, similar pathogen removal mechanisms are expected to occur in both processes. Just as turbidity monitoring is used to provide assurance that the removal credit assigned to a slow sand filter is being realized, EPA

is proposing continuous turbidity monitoring for all bank filtration wells that receive credit.

If monthly average turbidity levels (based on daily maximum values in the well) exceed 1 NTU, the system is required to report to the State and present an assessment of whether microbial removal has been compromised. If the State determines that microbial removal has been compromised, the system must not receive credit for bank filtration until the problem has been remediated. The turbidity performance requirement for bank filtration is less strict than that for slow sand filtration because, unlike slow sand filtration, bank filtration is a pre-treatment technique followed by conventional or direct filtration.

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Table IV-13.-- Summary Table Showing All Requirements for Bank Filtration Pre-treatment Log Removal Credit

Eligible for Bank Filtration Credit?	Yes, eligible for bank filtration credit (with continuous turbidity monitoring*) and State approval	No, not eligible for bank filtration credit
Some GWUDI Sites Eligible	• Unconsolidated, young, sandy**, granular aquifer	• Located in a hydrogeologic setting consisting of consolidated material
Some Water Collection Devices Eligible	• Vertical wells located greater than 25 feet (0.5 log credit) or 50 feet (1.0 log credit) from surface water • Horizontal wells with laterals that are no closer than 25 feet (0.5 log credit) or 50 feet (1.0 log credit) from the river channel under normal flow conditions	• Spring boxes • Infiltration galleries • Horizontal wells with laterals that extend within 25 feet of the river channel under normal flow conditions • Vertical wells located fewer than 25 feet from surface water (measured from the mapped FEMA floodway boundary)

*Average monthly turbidity values (based on daily maximum values) exceeding 1 NTU trigger an investigation by the system and consultation with the primacy agency

**Based on laboratory analysis of continuous core samples collected at the site; At least 90% of the recovered core length must contain intervals in which more than 10% of the grains are less than 1.0 mm in diameter.

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In summary, EPA believes that the measured full-scale field data from operating bank filtration systems, the turbidity monitoring provision, and the design criteria for aquifer material, collection device type, and setback distance, together provide assurance that the presumptive log removal credit will be achieved by bank filtration systems that conform to the requirements in today's proposal.

c. *Request for comment.* The Agency requests comment on the following issues concerning bank filtration:

• The performance of bank filtration in removing *Cryptosporidium* or surrogates to date at sites currently using this technology (*e.g.* sites with horizontal wells).

• The use of other methods (*e.g.*, geophysical methods such as ground penetrating radar) to complement or supplant core drilling to determine site suitability for bank filtration credit.

• The number of GWUDI systems in each State (*i.e.*, the number of systems having at least one GWUDI source) where bank filtration has been utilized as the primary filtration barrier (*e.g.*, no other physical removal technologies follow); also, the method that was used by the State to determine that each

system was achieving 2 log removal of *Cryptosporidium*.

• For GWUDI systems where natural or alternative filtration (*e.g.* bank filtration or artificial recharge) is used in combination with a subsequent filtration barrier (*e.g.*, bag or cartridge filters) to meet the 2 log *Cryptosporidium* removal requirement of the IESWTR or LT1ESWTR, how much *Cryptosporidium* removal credit has the State awarded (or is the State willing to grant if the bags/cartridges were found to be achieving < 2.0 logs) for the natural or alternative filtration process and how did the State determine this value?

• The proposed *Cryptosporidium* removal credit and associated design criteria, including any additional information related to this topic.

• Suitable separation distance(s) to be required between vertical or horizontal wells and adjacent surface water.

• Testing protocols and procedures for making site specific determinations of the appropriate level of *Cryptosporidium* removal credit to award to bank filtration processes.

• Information on the data and methods suitable for predicting *Cryptosporidium* removal based on the available data from surrogate and indicator measurements in water collection devices.

• The applicability of turbidity monitoring or other process monitoring procedures to indicate the ongoing performance of bank filtration processes.

7. Lime Softening

a. *What is EPA proposing today?* Lime softening is a drinking water treatment process that uses precipitation with lime and other chemicals to reduce hardness and enhance clarification prior to filtration. Lime softening can be categorized into two general types: (1) Single-stage softening, which is used to remove calcium hardness and (2) two-stage softening, which is used to remove magnesium hardness and greater levels of calcium hardness. A single-stage softening plant includes a primary clarifier and filtration components. A two-stage softening plant also includes a secondary clarifier located between the primary clarifier and filter. In some two-stage softening plants, a portion of the flow bypasses the first clarifier.

EPA has determined that lime softening plants in compliance with IESWTR or LT1ESWTR achieve a level of *Cryptosporidium* removal equivalent to conventional treatment plants (*i.e.*, average of 3 log). Consequently, lime softening plants that are placed in Bins 2–4 as a result of *Cryptosporidium* monitoring incur the same additional treatment requirements as conventional plants. However, EPA is proposing that two-stage softening plants be eligible for an additional 0.5 log *Cryptosporidium* treatment credit. To receive the 0.5 log credit, the plant must have a second clarification stage between the primary clarifier and filter that is operated continuously, and both clarification stages must treat 100% of the plant flow. In addition, a coagulant must be present in both clarifiers (may include metal salts, polymers, lime, or magnesium precipitation).

b. *How was this proposal developed?* The lime softening process is used to remove hardness, primarily calcium and magnesium, through chemical precipitation followed by sedimentation and filtration. The addition of lime increases pH, causing the metal ions to precipitate. Other contaminants can coalesce with the precipitates and be removed in the subsequent settling and filtration processes. While elevated pH has been shown to inactivate some microorganisms like viruses (Battigelli and Sobsey, 1993, Logsdon *et al.* 1994), current research indicates that *Cryptosporidium* and Giardia are not inactivated by high pH (Logsdon *et al.* 1994, Li *et al.* 2001). A two-stage lime softening plant has the potential for additional *Cryptosporidium* removal because of the additional sedimentation process.

Limited data are available on the removal of *Cryptosporidium* by the lime softening treatment process. EPA has evaluated data from a study by Logsdon *et al.* (1994), which investigated removal of Giardia and *Cryptosporidium* in full scale lime softening plants. In addition, the Agency has considered data provided by utilities on the removal of aerobic spores in softening plants. These data are summarized in the following paragraphs.

Logsdon *et al.* (1994) measured levels of *Cryptosporidium* and Giardia in the raw, settled, and filtered water of 13 surface water plants using lime softening. *Cryptosporidium* was detected in the raw water at 5 utilities: one single-stage plant and four two-stage plants. Using measured oocyst levels, *Cryptosporidium* removal by sedimentation was 1.0 log in the single-stage plant and 1.1 to 2.3 log in the two-stage plants. *Cryptosporidium* was found in two filtered water samples of the single stage plant, leading to calculated removals from raw to filtered water of 0.6 and 2.2 log. None of the two-stage plants had *Cryptosporidium* detected in the filtered water. Based on detection limits, calculated *Cryptosporidium* removals from raw to filtered water in the two-stage plants ranged from >2.67 to >3.85 log.

Giardia removal across sedimentation was >0.9 log for a single-stage plant and ranged from 0.8 to 3.2 log for two-stage plants, based on measured cyst levels. Removal of Giardia from raw water through filtration was calculated using detection limits as >1.5 log in a single-stage plant and ranged from >0.9 to >3.3 log in two-stage plants.

While results from the Logsdon *et al.* study are constrained by sample number and method detection limits, they suggest that two-stage softening plants may achieve greater removal of *Cryptosporidium* than single-stage plants. The authors concluded that two stages of sedimentation, each preceded by effective flocculation of particulate matter, may increase removal of protozoa. Additionally, the authors stated that consistent achievement of flocculation that results in effective settling in each sedimentation basin is the key factor in this treatment process.

Removal of Aerobic Spores by Softening Plants

Additional information on the microbial removal efficiency of the lime softening process comes from data provided by softening plants on removal of aerobic spores. While few treatment plants have sufficient concentrations of oocysts to directly calculate a *Cryptosporidium* removal efficiency, some plants have high concentrations of aerobic spores in the raw water. Spores may serve as an indicator of *Cryptosporidium* removal by sedimentation and filtration (Dugan *et al.* 2001).

The following two-stage softening plants provided data on removal of aerobic spores: St. Louis, MO, Kansas City, MO, and Columbus, OH (2 plants). *Cryptosporidium* data were also collected at these utilities, but it was not possible to calculate oocyst removal due to low raw water detection rates. Data on removal of aerobic spores by these softening plants is summarized in Table IV–14.

TABLE IV–14.—SUMMARY OF AEROBIC SPORE REMOVAL DATA FROM SOFTENING PLANTS

Plant	Mean log removal of aerobic spores		
	Primary clarifier	Secondary clarifier	Across plant*
St. Louis	1.7	1.1	3.8
Kansas City	2.4	0	3.4
Columbus Plant 1	1.2	1.6	3.1
Columbus Plant 2	1.3	2.4	4.2

*Excludes removal in pre-sedimentation basins; calculated spore removal may underestimate actual removal due to filter effluent levels below quantitation limits.

The City of St. Louis Water Division operates a two-stage lime softening process preceded by presedimentation. Ferric sulfate and polymer coagulants are added at various points in the process. St. Louis collected Bacillus subtilis spore samples between June 1998 and September 2000. During this time period, the mean spore concentration entering the softening process (*i.e.,* after presedimentation) was 8,132 cfu/100 mL. The log removal values shown in Table IV–14 are based on average spore concentrations following primary clarification, secondary clarification, and filtration. However, spore levels in some filtered water samples were below the method detection limit, so that the true mean spore removal across the plant may have been higher than indicated by the calculated value.

The Kansas City Water Services Department plant includes two-stage lime softening with pre-sedimentation and sludge recycle. Bacillus subtilis spore data were collected from this plant during January through November 2000. The mean spore concentration entering the lime softening process (after presedimentation) was 5,965 cfu/100 mL. Mean spore levels following primary clarification, secondary clarification, and filtration were 21.1, 25.7, and 2.6 cfu/100 mL, respectively. Corresponding log removal values are shown in Table IV–14. Note that the average spore concentration in the effluent of the secondary clarifier was essentially equivalent to the effluent of the primary clarifier, indicating that little removal occurred in the secondary clarifier. This result may have been due to the high removal achieved in the primary clarifier and, consequently, the relatively low concentration of spores entering the second clarifier. As with the St. Louis plant, many of the filtered water observations were below method detection limits, so actual log removal across the plant may have been higher than the calculated value.

The City of Columbus operates two lime softening plants, each of which has two clarification stages. Coagulant is added prior to the first clarification stage but lime is not added until the second clarifier (*i.e.,* first clarifier is not a softening stage). Between 1997 and 2000, samples for total aerobic spores were collected approximately monthly at each plant from raw water, following each clarification basin, and after filtration. Mean spore concentrations in the raw water sources for the two plants were 10,619 cfu/100 mL (Plant 1) and 22,595 cfu/100 mL (Plant 2). Mean log removals occurring in the two clarification stages and across the plant are shown for each plant in Table IV–14.

These data indicate that two-stage softening plants can remove high levels of *Cryptosporidium*, and, in particular, that a second clarification stage can achieve 0.5 log or greater removal. Three of the four plants that provided data on removal of aerobic spores achieved greater than 1 log reduction in the second clarifier. Kansas City, the one plant which achieved little removal in the second clarifier, achieved a mean 2.4 log removal in the primary clarifier. This was approximately 1 log more reduction than achieved in the primary clarifiers of the other three plants, so that the spore concentration entering the second clarifier in Kansas City may have been too low to serve as an indicator of removal efficiency. Consequently, EPA has concluded that these data support an additional *Cryptosporidium* treatment credit of 0.5 log for a two-stage softening plant.

EPA is proposing as a condition of the 0.5 log additional credit that a coagulant, which could include excess lime and soda ash or precipitation of magnesium hydroxide, be present in both clarifiers. This requirement is necessary to ensure that significant particulate removal occurs in both clarification stages. Logsdon *et al.* (1994) identified effective flocculation as being a key factor for removal of protozoa in softening plants. Among the softening plants that provided data on aerobic spore removal, St. Louis added ferric and polymer coagulants at different points in the process, and the two Columbus plants added lime to the second clarifier. Consequently, a requirement that plants add a coagulant, which may be lime, in the secondary clarifier is consistent with the data used to support the 0.5 log additional credit.

The Science Advisory Board (SAB) reviewed the proposed *Cryptosporidium* treatment credit for lime softening and supporting information, as presented in the November 2001 pre-proposal draft of the LT2ESWTR (USEPA 2001g). In written comments from a December 2001 meeting of the Drinking Water Committee, the SAB panel concluded that both single- and two-stage softening generally outperform conventional treatment due to the heavy precipitation that occurs. Further, the panel found that 0.5 log of additional *Cryptosporidium* removal is an average value for a two-stage lime softening plant. However, the SAB stated that the additional credit for two-stage softening should be given only if all the water passes through both stages. Today's proposal is consistent with these recommendations by the SAB.

EPA notes that by including a presumptive credit for softening plants, today's proposal differs from the Stage 2 M-DBP Agreement in Principle, which recommends up to 1 log additional *Cryptosporidium* treatment credit for softening plants based on demonstration of performance, but no additional presumptive credit.

c. *Request for comment.* EPA requests comment on the proposed criteria for awarding credit to lime softening plants. EPA would particularly appreciate comment on the following issues:

- Whether the information and analyses presented in this proposal supports an additional 0.5 log credit for two-stage softening, and the associated criteria necessary for credit.
- Additional information that either support or suggest modifications to the proposed criteria and credit.

8. Combined Filter Performance

a. *What is EPA proposing today?* This toolbox component will grant additional credit towards *Cryptosporidium*

treatment requirements to certain plants that maintain finished water turbidity at levels significantly lower than currently required. EPA is proposing to award an additional 0.5 log *Cryptosporidium* treatment credit to conventional and direct filtration plants that demonstrate a turbidity level in the combined filter effluent (CFE) less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. Compliance with this criterion must be based on measurements of the CFE every four hours (or more frequently) that the system serves water to the public. This credit is not available to membrane, bag/cartridge, slow sand, or DE plants, due to the lack of documented correlation between effluent turbidity and *Cryptosporidium* removal in these processes.

b. *How was this proposal developed?* Turbidity is an optical property measured from the amount of light scattered by suspended particles in a solution. It is a method defined parameter that can detect the presence of a wide variety of particles in water (e.g., clay, silt, mineral particles, organic and inorganic matter, and microorganisms), but it cannot provide specific information on particle type, number, or size. Turbidity is used as an indicator of raw and finished water quality and treatment performance. Turbidity spikes in filtered water indicate a potential for breakthrough of pathogens.

Under the IESWTR and LT1ESWTR, combined filter effluent turbidity in conventional and direct filtration plants must be less than or equal to 0.3 NTU in 95% of samples taken each month and must never exceed 1 NTU. These plants are also required to conduct continuous monitoring of turbidity for each individual filter, and provide an exceptions report to the State when certain criteria for individual filter effluent turbidity are exceeded (described in 63 FR 69487, December 16, 1998) (USEPA 1998a).

The Stage 2 M–DBP Advisory Committee recommended that systems receive an additional 0.5 log *Cryptosporidium* removal credit for maintaining 95th percentile combined filter effluent turbidity below 0.15 NTU, which is one half of the current required level of 0.3 NTU. In considering the technical basis to support this recommendation, EPA has reviewed studies that evaluated the efficiency of granular media filtration in removing *Cryptosporidium* when operating at different effluent turbidity levels.

For the IESWTR, EPA estimated that plants would target filter effluent turbidity in the range of 0.2 NTU in order to ensure compliance with a turbidity standard of 0.3 NTU. Similarly, EPA has estimated that plants relying on meeting a turbidity standard of 0.15 NTU in 95% of samples will consistently operate below 0.1 NTU in order to ensure compliance. Consequently, to assess the impact of compliance with the lower finished water turbidity standard, EPA compared *Cryptosporidium* removal efficiency when effluent turbidity is below 0.1 NTU with removal efficiency when effluent turbidity is in the range of 0.1 to 0.2 NTU. Results from applicable studies are summarized in Table IV–15 and are discussed in the following paragraphs.

TABLE IV–15.—STUDIES OF *Cryptosporidium* REMOVAL AT DIFFERENT EFFLUENT TURBIDITY LEVELS

Microorganism	Average of log removals	Filtered effluent turbidity	Experiment design	Researcher
Cryptosporidium	4.39	≤0.1 NTU	Pilot-scale	Patania et al. (1995).
	3.55	>0.1 and ≤0.2 NTU		
Giardia	4.23	≤0.1 NTU		
	3.22	>0.1 and ≤0.2 NTU		
Cryptosporidium	4.09	≤0.1 NTU	Bench-scale	Emelko et al. (1999).
	3.58	>0.1 and ≤0.2 NTU		
Cryptosporidium	3.76	≤0.1 NTU	Pilot-scale	Dugan et al. (2001).
	2.56	>0.1 and ≤0.2 NTU		

Patania *et al.* (1995) conducted pilot-scale studies at four locations to evaluate the removal of seeded *Cryptosporidium* and Giardia, turbidity, and particles. Treatment processes, coagulants, and coagulant doses differed among the four locations. Samples of filter effluent were taken at times of stable operation and filter maturation. Analysis of summary data from the seeded runs at all locations shows that average *Cryptosporidium* removal was greater by more than 0.5 log when effluent turbidity was less than 0.1 NTU, in comparison to removal with effluent turbidity in the range 0.1 to 0.2 NTU (see Table IV–15).

Emelko *et al.* (1999) used a bench scale dual media filter to study *Cryptosporidium* removal during both optimal and challenged operating conditions. Water containing a suspension of kaolinite (clay) was spiked with oocysts, coagulated in-line with alum, and filtered. Oocyst removal was evaluated during stable operation when effluent turbidity was below 0.1 NTU. Removal was also measured after a hydraulic surge that caused process upset, and with coagulant addition terminated. These later two conditions resulted in effluent turbidities greater than 0.1 NTU and decreased removal of *Cryptosporidium*. As shown in Table IV–15, average removal of *Cryptosporidium* during periods with effluent turbidity below 0.1 NTU was approximately 0.5 log greater than when effluent turbidity was between 0.1 to 0.2 NTU.

Dugan *et al.* (2001) evaluated *Cryptosporidium* removal in a pilot scale conventional treatment plant. Sixteen filtration runs seeded with *Cryptosporidium* were conducted at different raw water turbidities and coagulation conditions. Eleven of the runs had an effluent turbidity below 0.1 NTU, and five runs had effluent turbidity between 0.1 and 0.2 NTU. For runs where the calculated *Cryptosporidium* removal was concentration limited (*i.e.*, effluent values were non-detect), the method detection limit was used to calculate the values shown in Table IV–15. Using this conservative estimate, average *Cryptosporidium* removal with effluent turbidity below 0.1 NTU exceeded by more than 1 log the average removal observed with effluent turbidity between 0.1 to 0.2 NTU.

In summary, these three studies all support today's proposal in showing that plants consistently operating below 0.1 NTU can achieve an additional 0.5 log or greater removal of *Cryptosporidium* than when operating between 0.1 and 0.2 NTU. Because EPA expects plants relying on compliance with a 0.15 NTU standard will consistently operate below 0.1 NTU, the

Agency has determined it is appropriate to propose an additional 0.5 log treatment credit for plants meeting this standard.

The SAB reviewed the proposed additional 0.5 log *Cryptosporidium* removal credit for systems maintaining very low CFE turbidity, as presented in the November 2001 pre-proposal draft of the LT2ESWTR (USEPA 2001g). The SAB also reviewed a potential additional 1.0 log *Cryptosporidium* removal credit for systems achieving very low individual filter effluent (IFE) turbidity, which is addressed in section IV.C.16 of today's proposal.

In written comments from a December 2001 meeting of the Drinking Water Committee, the SAB panel stated that additional credit for lower finished water turbidity is consistent with what is known in both pilot and full-scale operational experiences for *Cryptosporidium* removal. Recognizing that IESWTR requirements for lowering turbidity in the treated water will result in lower concentrations of *Cryptosporidium*, the panel affirmed that even further lowering of turbidity will result in further reductions in *Cryptosporidium* in the filter effluent. However, the SAB concluded that limited data were presented to show the exact removal that can be achieved, and recommended that no additional credit be given to plants that demonstrate CFE turbidity of 0.15 NTU or less. The SAB recommended that 0.5 log credit be given to plants achieving IFE turbidity in each filter less than 0.15 NTU in 95% of samples each month.

In responding to this recommendation from the SAB, EPA acknowledges the difficulty in precisely quantifying *Cryptosporidium* removal through filtration based on effluent turbidity levels. Nevertheless, EPA finds that available data consistently show that removal of *Cryptosporidium* is increased by 0.5 log or greater when filter effluent turbidity is reduced to levels reflecting compliance with a 0.15 NTU standard, in comparison to compliance with a 0.3 NTU standard. Consequently, EPA has concluded that it is appropriate to propose this 0.5 log presumptive treatment credit for systems achieving very low CFE turbidity.

Measurement of Low Level Turbidity

Another important aspect of proposing to award additional removal credit for lower finished water turbidity is the performance of turbidimeters in measuring turbidity below 0.3 NTU. The following paragraphs summarize results from several studies that evaluated low level measurement of turbidity by different on-line and bench top instruments. Note that because compliance with the CFE turbidity limit is based on 4-hour readings, either on-line or bench top turbidimeters may be used. EPA believes that results from these studies indicate that currently available turbidity monitoring equipment is capable of reliably assessing turbidity at levels below 0.1 NTU, provided instruments are well calibrated and maintained.

The 1997 NODA for the IESWTR (67 FR 59502, Nov. 3, 1997) (USEPA 1997a) discusses issues relating to the accuracy and precision of low level turbidity measurements. This document cites studies (Hart *et al.* 1992, Sethi *et al.* 1997) suggesting that large tolerances in instrument design criteria have led to turbidimeters that provide different turbidity readings for a given suspension.

At the time of IESWTR NODA, EPA had conducted performance evaluation (PE) studies of turbidity samples above 0.3 NTU. A subsequent PE study (USEPA 1998e), labeled WS041, was carried out to address concern among the Stage 1 M–DBP Federal Advisory Committee regarding the ability to reliably measure lower turbidity levels. The study involved distribution of different types of laboratory prepared standard solutions with reported turbidity values of 0.150 NTU or 0.160 NTU. The results of this study are summarized in Table IV–16.

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Table IV-16.-- Performance Evaluation - WS041 Data for Low Level Turbidity Analysis (USEPA 1998e)

Type of Instrument	Sample Solution Type	"True" Value (NTU)	No. of Results Available	Mean* (NTU)	Std. Dev* (NTU)	95% Prediction Interval (NTU)
Bench Top	Polystyrene Spheres	0.150	292	0.203	0.0558	0.093-0.313
Portable or IR	Polystyrene Spheres	0.150	340	0.200	0.0439	0.113–0.286
Portable or IR	Formazin	0.160	335	0.176	0.0431	0.091-0.261
On-Line	Polystyrene Spheres	0.150	52	0.228	0.0773	0.072-0.385

*Calculated using biweight transformation

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The data summarized in Table IV–16 indicate a positive bias for all instruments when compared against a reported ''true value.'' On-line instruments in this study had a larger positive bias and higher standard deviation (RSD approximately 50 percent). The positive bias is consistent with previous PE studies (USEPA 1998e) and suggests that error in turbidimeter readings may be generally conservative (*i.e.,* systems will operate

at lower than required effluent turbidity levels).

Letterman *et al.* (2001) evaluated the effect of turbidimeter design and calibration methods on *inter*-instrument performance, comparing bench top to on-line instruments and instruments within each of those categories from different manufacturers. The study used treated water collected from the filter effluent of water treatment plants. Reported sample turbidity values ranged from 0.05 to 1 NTU. Samples were analyzed in a laboratory environment. The results are consistent with those of the WS041 study, specifically the positive bias of on-line instruments. However, Letterman *et al.* found generally poor agreement among different on-line instruments and between bench-top and on-line instruments. The authors also observed that results were independent of the calibration method, though certain experiments suggested that analyst experience may have some effect on turbidity readings from bench-top instruments.

Sadar (1999) conducted an *intra*-instrument study of low level turbidity measurements among instruments from the same manufacturer. This study was performed under well-controlled laboratory conditions. *Intra*-instrument variation among different models and between bench top and on-line instruments occurred but at significantly lower levels than the Letterman *et al. inter*-instrument study. Newer instruments also tended to read lower than older instruments, which the author attributed to a reduction in stray light and lower sensitivities in the newer instruments. Sadar also found a generally positive bias when comparing on-line to bench-top and when comparing all instruments to a prepared standard.

The American Society for Testing and Materials (ASTM) has issued standard test methods for measurement of turbidity below 5 NTU by on-line (ASTM 2001) and static (ASTM 2003) instrument modes. The methods specify that the instrument should permit detection of turbidity differences of 0.01 NTU or less in waters having turbidities of less than 1.00 NTU (ASTM 2001) and 5.0 NTU (ASTM 2003), respectively. *Inter*-laboratory study data included with the method for a known turbidity standard of 0.122 NTU show an analyst relative deviation of 7.5% and a laboratory relative deviation of 16% (ASTM 2003).

In summary, the data collected in these studies of turbidity measurement indicate that currently available monitoring equipment can reliably measure turbidity at levels of 0.1 NTU and lower. However, this requires rigorous calibration and verification procedures, as well as diligent maintenance of turbidity monitoring equipment (Burlingame 1998, Sadar 1999). Systems that pursue additional treatment credit for lower finished water turbidity must develop the procedures necessary to ensure accurate and reliable measurement of turbidity at levels of 0.1 NTU and less. EPA guidance for the microbial toolbox will provide direction to water systems on developing these procedures.

c. *Request for comment.* EPA invites comment on the following issues regarding the proposed *Cryptosporidium* treatment credit for combined filter performance:

- Do the studies cited here support awarding 0.5 log credit for CFE ≤ 0.15 NTU 95% of the time?
- Does currently available turbidity monitoring technology accurately distinguish differences between values measured near 0.15 NTU?

9. Roughing Filter

a. *What is EPA proposing today?* The Stage 2 M–DBP Agreement in Principle recommends a 0.5 log presumptive credit towards additional *Cryptosporidium* treatment requirements for roughing filters. However, the Agreement further specifies that EPA is to determine the design and implementation criteria under which the credit would be awarded. Upon subsequent review of available literature, EPA is unable to identify design and implementation conditions for roughing filters that would provide reasonable assurance of achieving a 0.5 log removal of oocysts. Consequently, EPA is not proposing presumptive credit for *Cryptosporidium* removal by roughing filters. Today's proposal does, though, include a 0.5 log credit for a second granular media filter following coagulation and primary filtration (see section IV.C.13).

b. *How was this proposal developed?* Roughing filtration is a technique used primarily in developing countries to remove solids from high turbidity source waters prior to treatment with slow sand filters. Typically, roughing filters consist of a series of sedimentation tanks filled with progressively smaller diameter media in the direction of flow. The media can be gravel, plastic, crushed coconut, rice husks, or a similar locally available material. The flow direction in roughing filters can be either horizontal or vertical, and vertical roughing filters can be either upflow or downflow. The media in the tanks effectively reduce the vertical settling distance of particles to a distance of a few millimeters. As sediment builds on the media, it eventually sloughs off and begins to accumulate in the lower section of the filter, while simultaneously regenerating the upper portions of the filter. The filters require periodic cleaning to remove the collected silt.

Review of the scientific and technical literature pertaining to roughing filters has identified no information on removal of *Cryptosporidium*. Information is available on removal of suspended solids, turbidity, particles, fecal coliforms and some algae, but none of these has been demonstrated to be an indicator of *Cryptosporidium* removal by roughing filters. Moreover, roughing filters are not preceded by a coagulation step, and studies have found that some potential surrogates, such as aerobic spores, are not conservative indicators of *Cryptosporidium* removal by filtration when a coagulant is not present (Yates *et al.* 1998, Dugan *et al.* 2001). Thus, it is unclear how to relate results from studies of the removal of other particles by roughing filters to potential removal of *Cryptosporidium*.

In addition, some studies have observed very poor removal of *Cryptosporidium* by rapid sand filters when a coagulant is not used (Patania *et al.* 1995, Huck *et al.* 2000). Based on these findings, it is expected that there would be situations where a roughing filter would not achieve 0.5 log *Cryptosporidium* removal. Because available data are insufficient to determine the conditions that would be necessary for a roughing filter to achieve 0.5 log *Cryptosporidium* removal, EPA is unable to propose this credit. The following discussion describes four studies that analyzed the effectiveness of roughing filters for removing solids, turbidity, particles, fecal coliforms, and algae.

Wegelin *et al.* (1987) conducted pilot-scale studies on the use of horizontal roughing filters to reduce solids, turbidity, and particles. Testing was performed to determine the influence of different design parameters on filter performance. Data from the parameter testing was used to establish an empirical model to simulate filtrate quality as a function of filter length and time for a given filter configuration. Using the mathematical model, the researchers found that long filters (10 m) at low filtration rates (0.5 m/h) were capable of reducing high suspended solids concentrations (1000 mg/L TSS) down to less than 3 mg/L.

Further work by Wegelin (1988) evaluated roughing filters as pretreatment for slow sand filters for

waters with variable and seasonably high suspended solids concentrations. This study collected data on roughing filters in Peru, Colombia, Sudan, and Ghana. Table IV–17 summarizes data for three of the roughing filters. These filters were capable of reducing peak turbidities by 80 to 90 percent. Further, the Peruvian and Colombian filters reduced fecal coliforms by 77 and 89 percent, respectively. The Sudanese filter may have removed around 90 percent of the fecal coliforms, but specific values were not given. Data collected from roughing filters in Ghana on algae removal indicate that the Merismopedia (0.5 μm) and Chlorophyta (2–10 μm), which are comparable in size to *Cryptosporidium* oocysts, were completely removed from the water in mature filters, and that some removal of Chlorophyta, but not Merismopedia, occurred in filters after three days of operation. However, the removal of these organisms has not been correlated with *Cryptosporidium* oocyst removal.

TABLE IV–17.—ROUGHING FILTER DATA FROM WEGELIN, 1988

Location	Azpita, Peru	El Retiro, Colombia	Blue Nile Health Project, Sudan
Roughing Filter Type	Downflow	Upflow (multi-layer filter)	Horizontal-flow.
Filtration Rate	0.30 m/h (0.98 ft/hr)	0.74 m/h (2.43 f/hr)	0.3 m/h (0.98 ft/hr).
Design Capacity	35 m^3/d	790 m^3/d	5 m^3/d.
Turbidity (NTU)			
Raw Water	50–200	10–150	40–500
Roughing Filter Effluent	15–40	5–15	5–50
Fecal Coliforms (/100 mL)			
Raw Water	700	16,000	>300
Roughing Filter Effluent	160	1,680	<25

oller (1993) details the mechanisms of particle removal that occur in roughing filters. The conclusions are similar to those drawn by Wegelin *et al.* (1987). Particle analysis reviewed by Boller indicates that after seven days of operation, the four stage pilot filter utilized by Wegelin *et al.* (1987) removed more than 98 percent of particles sized 1.1 μm, and greater than 99 percent of particles sized 3.6 μm. After 62 days, only 80 percent of particles sized 1.1 μm were removed, while 90 percent of particles sized 3.6 μm were removed. Boller did not give the solids loading on the tested filter, and particle removal was not correlated to *Cryptosporidium* oocyst removal.

Collins *et al.* (1994) investigated solids and algae removal with pilot scale vertical downflow roughing filters. Gravel media size, filter depth, and flow rate were varied to determine which design variables had the greatest effect on filter performance. Results indicated that the most influential design parameters for removing solids from water, in order of importance, were filter length, gravel size, and hydraulic flow rate. For algae removal, the most influential design parameters were hydraulic flow rate, filter length, and gravel size. Solids removal was better in filters that had been ripened with algae for 5–7 days. However, extrapolation of these results to *Cryptosporidium* removal could not be made.

c. *Request for comment.* The Agency requests comment on the information that has been presented about roughing filters, and specifically the question of whether and under what conditions roughing filters should be awarded a 0.5 log credit for removal of *Cryptosporidium*. EPA also requests information on specific studies of *Cryptosporidium* oocyst removal by roughing filters, or from studies of the removal of surrogate parameters that have been shown to correlate with oocyst removal in roughing filters.

10. Slow Sand Filtration

a. *What is EPA proposing today?* Slow sand filtration is defined in 40 CFR 141.2 as a process involving passage of raw water through a bed of sand at low velocity (generally less than 0.4 m/h) resulting in substantial particulate removal by physical and biological mechanisms. Today's proposal allows systems using slow sand filtration as a secondary filtration step following a primary filtration process (*e.g.*, conventional treatment) to receive an additional 2.5 log *Cryptosporidium* treatment credit. There must be no disinfectant residual in the influent water to the slow sand filtration process to be eligible for credit.

Note that this proposed credit differs from the credit proposed for slow sand filtration as a primary filtration process. EPA has concluded, based on treatment studies described in section III.D, that plants using well designed and well operated slow sand filtration as a primary filtration process can achieve an average *Cryptosporidium* removal of 3 log (Schuler and Ghosh, 1991, Timms *et al.* 1995, Hall *et al.* 1994). Consequently, as described in section IV.A, EPA is proposing that plants using slow sand filtration as a primary filtration process receive a 3 log credit towards *Cryptosporidium* treatment requirements associated with Bins 2–4 under the LT2ESWTR (*i.e.*, credit equivalent to a conventional treatment plant).

The proposed 2.5 log credit for slow sand filtration as part of the microbial toolbox applies only when it is used as a secondary filtration step, following a primary filtration process like conventional treatment. While the removal mechanisms that make slow sand filtration effective as a primary filtration process would also be operative when used as a secondary filtration step, EPA has little data on this specific application. The Agency is proposing 2.5 log credit for slow sand filtration as a secondary filtration step, in comparison to 3 log credit as a primary filtration process, as a conservative measure reflecting greater uncertainty. In addition, the proposed 2.5 log credit for slow sand filtration as part of the microbial toolbox is consistent with the recommendation in the Stage 2 M–DBP Agreement in Principle.

b. *How was this proposal developed?* The Stage 2 M–DBP Agreement in Principle recommends that slow sand filtration receive 2.5 log or greater *Cryptosporidium* treatment credit when used in addition to existing treatment that achieves compliance with the

IESWTR or LT1ESWTR. Slow sand filtration is not typically used as a secondary filtration step following conventional treatment or other primary filtration processes of similar efficacy. However, EPA expects that slow sand filtration would achieve significant removal of *Cryptosporidium* in such a treatment train.

While there is a significant body of data demonstrating the effectiveness of slow sand filtration for *Cryptosporidium* removal as a primary filtration process, as described in section III.D, EPA has limited data on the effectiveness of slow sand filtration when used as a secondary filtration step. Hall *et al.* (1994) evaluated oocyst removal for a pilot scale slow sand filter following a primary filtration process identified as a rapid gravity filter. The combined treatment train of a primary filtration process followed by slow sand filtration achieved greater than 3 log *Cryptosporidium* removal in three of five experimental runs, while approximately 2.5 log reduction was observed in the other two runs. In comparison, Hall *et al.* (1994) reported slow sand filtration alone to achieve at least a 3 log removal of oocysts in each of four experimental runs when not preceded by a primary filtration process. The authors offered no explanation for these results, but measured oocyst removals may have been impacted by limitations with the analytical method.

Removal of microbial pathogens in slow sand filters is complex and is believed to occur through a combination of physical, chemical, and biological mechanisms, both on the surface (schmutzdecke) and in the interior of the filter bed. It is unknown if the higher quality of the water that would be influent to a slow sand filter when used as a secondary filtration step would impact the efficiency of the filter in removing *Cryptosporidium*. Based on the limited data on the performance of slow sand filtration as a secondary filtration step, and in consideration of the recommendation of the Advisory Committee, EPA is proposing only a 2.5 log additional *Cryptosporidium* treatment credit for this application.

c. *Request for comment.* The Agency requests comment on whether the available data are adequate to support awarding a 2.5 log *Cryptosporidium* removal credit for slow sand filtration applied as a secondary filtration step, along with any additional information related to this application.

11. Membrane Filtration

a. *What is EPA proposing today?* EPA is proposing criteria for awarding credit to membrane filtration processes for removal of *Cryptosporidium*. To receive removal credit, the membrane filtration process must: (1) Meet the basic definition of a membrane filtration process, (2) have removal efficiency established through challenge testing and verified by direct integrity testing, and (3) undergo periodic direct integrity testing and continuous indirect integrity monitoring during use. The maximum removal credit that a membrane filtration process is eligible to receive is equal to the lower value of either:

—The removal efficiency demonstrated during challenge testing OR

—The maximum log removal value that can be verified through the direct integrity test (*i.e.*, integrity test sensitivity) used to monitor the membrane filtration process.

By the criteria in today's proposal, a membrane filtration process could potentially meet the Bin 4 *Cryptosporidium* treatment requirements of this proposal. These criteria are described in more detail below. EPA is developing a Membrane Filtration Guidance Manual that provides additional information and procedures for meeting these criteria (USEPA 2003e). A draft of this guidance is available in the docket for today's proposal (*http://www.epa.gov/edocket/*).

Definition of a Membrane Filtration Process

For the purpose of this proposed rule, membrane filtration is defined as a pressure or vacuum driven separation process in which particulate matter larger than 1 μm is rejected by a nonfibrous, engineered barrier, primarily through a size exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test. This definition is intended to include the common membrane technology classifications: microfiltration (MF), ultrafiltration (UF), nanofiltration (NF), and reverse osmosis (RO). MF and UF are low-pressure membrane filtration processes that are primarily used to remove particulate matter and microbial contaminants. NF and RO are membrane separation processes that are primarily used to remove dissolved contaminants through a variety of mechanisms, but which also remove particulate matter via a size exclusion mechanism.

In today's proposal, the critical distinction between membrane filtration processes and bag and cartridge filters, described in section IV.C.12, is that the integrity of membrane filtration processes can be directly tested. Based on this distinction, EPA is proposing that membrane material configured into a cartridge filtration device that meets the definition of membrane filtration and that can be direct integrity tested according to the criteria specified in this section is eligible for the same removal credit as a membrane filtration process.

Membrane devices can be designed in a variety of configurations including hollow-fiber modules, hollow-fiber cassettes, spiral-wound elements, cartridge filter elements, plate and frame modules, and tubular modules among others. In today's proposal, the generic term module is used to refer to all of these various configurations and is defined as the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure. A membrane unit is defined as a group of membrane modules that share common valving that allows the unit to be isolated from the rest of the system for the purpose of integrity testing or other maintenance.

Challenge Testing

A challenge test is defined as a study conducted to determine the removal efficiency (*i.e.*, log removal value) of the membrane filtration media. The removal efficiency demonstrated during challenge testing establishes the maximum removal credit that a membrane filtration process is eligible to receive, provided this value is less than or equal to the maximum log removal value that can be verified by the direct integrity test (as described in the following subsection). Challenge testing is a product specific rather than a site specific requirement. At the discretion of the State, data from challenge studies conducted prior to promulgation of this regulation may be considered in lieu of additional testing. However, the prior testing must have been conducted in a manner that demonstrates a removal efficiency for *Cryptosporidium* commensurate with the treatment credit awarded to the process. Guidance for conducting challenge testing to meet the requirements of the rule is provided in the Membrane Filtration Guidance Manual (USEPA 2003e). Challenge testing must be conducted according to the following criteria:

• Challenge testing must be conducted on a full-scale membrane module identical in material and construction to the membrane modules proposed for use in full-scale treatment facilities. Alternatively, challenge testing may be conducted on a smaller membrane module, identical in material and similar in construction to the full-

scale module, if testing meets the other requirements listed in this section.

- Challenge testing must be conducted using *Cryptosporidium* oocysts or a surrogate that has been determined to be removed no more efficiently than *Cryptosporidium* oocysts. The organism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate must be determined using a method capable of discretely quantifying the specific challenge particulate used in the test. Thus, gross water quality measurements such as turbidity or conductivity cannot be used.
- The maximum allowable feed water concentration used during a challenge test is based on the detection limit of the challenge particulate in the filtrate, and is determined according to the following equation:

$$\text{Maximum Feed Concentration} = 3.16 \times 10^6 \times (\text{Filtrate Detection Limit})$$

This will allow the demonstration of up to 6.5 log removal during challenge testing if the challenge particulate is removed to the detection limit.

- Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design system recovery as specified by the manufacturer. Flux is defined as the flow per unit of membrane area. Recovery is defined as the ratio of filtrate volume produced by a membrane to feed water volume applied to a membrane over the course of an uninterrupted operating cycle. An operating cycle is bounded by two consecutive backwash or cleaning events. In the context of this rule, recovery does not consider losses that occur due to the use of filtrate in backwashing or cleaning operations.
- Removal efficiency of a membrane filtration process is determined from the results of the challenge test, and expressed in terms of log removal values as defined by the following equation:

$$LRV = LOG_{10}(C_f) - LOG_{10}(C_p)$$

where LRV = log removal value demonstrated during challenge testing; C_f = the feed concentration used during the challenge test; and C_p = the filtrate concentration observed during the challenge test. For this equation to be valid, equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, then the term C_p is set equal to the detection limit. A single LRV is calculated for each membrane module evaluated during the test.

- The removal efficiency of a membrane filtration process demonstrated during challenge testing is expressed as a log removal value (LRV_{C-Test}). If fewer than twenty modules are tested, then LRV_{C-Test} is assigned a value equal to the lowest of the representative LRVs among the various modules tested. If twenty or more modules are tested, then LRV_{C-Test} is assigned a value equal to the 10th percentile of the representative LRVs among the various modules tested. The percentile is defined by [i/(n+1)] where i is the rank of n individual data points ordered lowest to highest. It may be necessary to calculate the 10th percentile using linear interpolation.
- A quality control release value (QCRV) must be established for a non-destructive performance test (*e.g.*, bubble point test, diffusive airflow test, pressure/vacuum decay test) that demonstrates the *Cryptosporidium* removal capability of the membrane module. The performance test must be applied to each production membrane module that did not undergo a challenge test in order to verify *Cryptosporidium* removal capability. Production membrane modules that do not meet the established QCRV are not eligible for the removal credit demonstrated during challenge testing.
- Any significant modification to the membrane filtration device (*e.g.*, change in the polymer chemistry of the membrane) requires additional challenge testing to demonstrate removal efficiency of the modified module and to define a new QCRV for the nondestructive performance test.

Direct Integrity Testing

In order to receive removal credit for *Cryptosporidium*, the removal efficiency of a membrane filtration process must be routinely verified through direct integrity testing. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches. An integrity breach is defined as one or more leaks that could result in contamination of the filtrate. The direct integrity test method must be applied to the physical elements of the entire membrane unit including membranes, seals, potting material, associated valving and piping, and all other components which under compromised conditions could result in contamination of the filtrate.

The direct integrity tests commonly used at the time of this proposal include those that use an applied pressure or vacuum (such as the pressure decay test and diffusive airflow test), and those that measure the rejection of a particulate or molecular marker (such as spiked particle monitoring). Today's proposal does not stipulate the use of a particular direct integrity test. Instead, the direct integrity test must meet performance criteria for resolution, sensitivity, and frequency.

Resolution is defined as the smallest leak that contributes to the response from a direct integrity test. Any direct integrity test applied to meet the requirements of this proposed rule must have a resolution of 3 μm or less. The manner in which the resolution criterion is met will depend on the type of direct integrity test used. For example, a pressure decay test can meet the resolution criterion by applying a net test pressure great enough to overcome the bubble point of a 3 μm hole. A direct integrity test that uses a particulate or molecular marker can meet the resolution criterion by applying a marker of 3 μm or smaller.

Sensitivity is defined as the maximum log removal value that can be reliably verified by the direct integrity test (LRV_{DIT}). The sensitivity of the direct integrity test applied to meet the requirements of this proposed rule must be equal to or greater than the removal credit awarded to the membrane filtration process. The manner in which LRV_{DIT} is determined will depend on the type of direct integrity test used. Direct integrity tests that use an applied pressure or vacuum typically measure the rate of pressure/vacuum decay or the flow of air through an integrity breach. The response from this type of integrity test can be related to the flow of water through an integrity breach (Q_{breach}) during normal operation, using procedures such as those described in the Membrane Filtration Guidance Manual (USEPA 2003e). Once Q_{breach} has been determined, a simple dilution model is used to calculate LRV_{DIT} for the specific integrity test application, as shown by the following equation:

$$LRV_{DIT} = LOG_{10}(Q_p/(VCF \times Q_{breach}))$$

where LRV_{DIT} = maximum log removal value that can be verified by a direct integrity test; Q_p = total design filtrate flow from the membrane unit; Q_{breach} = flow of water from an integrity breach associated with the smallest integrity test response that can be reliably measured; and VCF = volumetric concentration factor.

The volumetric concentration factor is the ratio of the suspended solids concentration on the high pressure side of the membrane relative to the feed water, and is defined by the following equation:

$$VCF = C_m/C_f$$

where C_m is the concentration of particulate matter on the high pressure

side of the membrane that remains in suspension; and C_f is the concentration of suspended particulate matter in the feed water. The magnitude of the concentration factor depends on the mode of system operation and typically ranges from 1 to 20. The Membrane Filtration Guidance Manual presents approaches for determining the volumetric concentration factor for different operating modes (USEPA 2003e).

Sensitivity of direct integrity tests that use a particulate or molecular marker is determined from the feed and filtrate concentrations of the marker. The LRV_{DIT} for this type of direct integrity test is calculated according to the following equation:

$$LRV_{DIT} = LOG_{10}(C_f) - LOG_{10}(C_p)$$

where LRV_{DIT} = maximum log removal value that can be verified by a direct integrity test; C_f = the typical feed concentration of the marker used in the test; and C_p = the filtrate concentration of the marker from an integral membrane unit. For this equation to be valid, equivalent units must be used for the feed and filtrate concentrations. An ideal particulate or molecular marker would be completely removed by an integral membrane unit.

If the sensitivity of the direct integrity test is such that LRV_{DIT} is less than $LRV_{C\text{-}Test}$, LRV_{DIT} establishes the maximum removal credit that a membrane filtration process is eligible to receive. Conversely, if LRV_{DIT} for a direct integrity test is greater than $LRV_{C\text{-}Test}$, $LRV_{C\text{-}Test}$ establishes the maximum removal credit.

A control limit is defined as an integrity test response which, if exceeded, indicates a potential problem with the system and triggers a response. Under this proposal, a control limit for a direct integrity test must be established that is indicative of an integral membrane unit capable of meeting the *Cryptosporidium* removal credit awarded by the State. If the control limit for the direct integrity test is exceeded, the membrane unit must be taken off-line for diagnostic testing and repair. The membrane unit could only be returned to service after the repair has been completed and confirmed through the application of a direct integrity test.

The frequency of direct integrity testing specifies how often the test is performed over an established time interval. Most direct integrity tests available at the time of this proposal are applied periodically and must be conducted on each membrane unit at a frequency of not less than once every 24 hours while the unit is in operation. If continuous direct integrity test methods become available that also meet the sensitivity and resolution criteria described earlier, they may be used in lieu of periodic testing.

EPA is proposing that at a minimum, a monthly report must be submitted to the State summarizing all direct integrity test results above the control limit associated with the *Cryptosporidium* removal credit awarded to the process and the corrective action that was taken in each case.

Continuous Indirect Integrity Monitoring

The majority of currently available direct integrity test methods are applied periodically since the membrane unit must be taken out of service to conduct the test. In order to provide some measure of process performance between direct integrity testing events, continuous indirect integrity monitoring is required. Indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter. If a continuous direct integrity test is implemented that meets the resolution and sensitivity criteria described previously, continuous indirect integrity monitoring is not required. Continuous indirect integrity monitoring must be conducted according to the following criteria:

- Unless the State approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring.
- Continuous monitoring is defined as monitoring conducted at a frequency of no less than once every 15 minutes.
- Continuous monitoring must be separately conducted on each membrane unit.
- If indirect integrity monitoring includes turbidity and if the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes (*i.e.*, two consecutive 15-minute readings above 0.15 NTU), direct integrity testing must be performed on the associated membrane units.
- If indirect integrity monitoring includes a State-approved alternative parameter and if the alternative parameter exceeds a State-approved control limit for a period greater than 15 minutes, direct integrity testing must be performed on the associated membrane units.
- EPA is proposing that at a minimum, a monthly report must be submitted to the primacy agency summarizing all indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken in each case.

b. *How was this proposal developed?* The Stage 2 M–DBP Agreement in Principle recommends that EPA develop criteria to award *Cryptosporidium* removal credit to membrane filtration processes. Today's proposal and the supporting guidance are consistent with the Agreement.

A number of studies have been conducted which have demonstrated the ability of membrane filtration processes to remove pathogens, including *Cryptosporidium*, to below detection levels. A literature review summarizing the results of several comprehensive studies was conducted by EPA and is presented in Low-Pressure Membrane Filtration for Pathogen Removal: Application, Implementation, and Regulatory Issues (USEPA 2001h). Many of these studies used *Cryptosporidium* seeding to demonstrate removal efficiencies as high as 7 log. The collective results from these studies demonstrate that an integral membrane module, *i.e.*, a membrane module without any leaks or defects, with an exclusion characteristic smaller than *Cryptosporidium*, is capable of removing this pathogen to below detection in the filtrate, independent of the feed concentration.

Some filtration devices have used membrane media in a cartridge filter configuration; however, few data are available documenting their ability to meet the requirements for membrane filtration described in section IV.C.11.a of this preamble. However, in one study reported by Dwyer *et al.* (2001), a membrane cartridge filter demonstrated *Cryptosporidium* removal efficiencies in excess of 6 log. This study illustrates the potentially high removal capabilities of membrane filtration media configured into a cartridge filtration device, thus providing a basis for awarding removal credits to these devices under the membrane filtration provision of the rule, assuming that the device meets the definition of a membrane filtration process as well as the direct integrity test requirements.

Today's proposal requires challenge testing of membrane filtration processes used to remove *Cryptosporidium*. As noted in section III.D, EPA believes this is necessary due to the proprietary nature of these systems and the lack of any uniform criteria for establishing the exclusion characteristic of a membrane. Challenge testing addresses the lack of a standard approach for characterizing membranes by requiring direct verification of removal efficiency. The proposed challenge testing is product-specific and not site-specific since the

intent of this testing is to demonstrate the removal capabilities of the membrane product rather than evaluate the feasibility of implementing membrane treatment at a specific plant.

Testing can be conducted using a full-scale module or a smaller module if the results from the small-scale module test can be related to full-scale module performance. Most challenge studies presented in the literature have used full-scale modules, which provide results that can be directly related to full-scale performance. However, use of smaller modules is considered feasible in the evaluation of removal efficiency, and a protocol for challenge testing using small-scale modules has been proposed (NSF, 2002a). Since the removal efficiency of an integral membrane is a direct function of the membrane material, it may be possible to use a small-scale module containing the same membrane fibers or sheets used in full-scale modules for this evaluation. However, it will be necessary to relate the results of the small-scale module test to the nondestructive performance test quality control release value that will be used to validate full-scale production modules.

Challenge testing with either *Cryptosporidium* oocysts or a surrogate is permitted. Challenge testing with *Cryptosporidium* clearly provides direct verification of removal efficiency for this pathogen; however, several studies have demonstrated that surrogates can provide an accurate or conservative measure of *Cryptosporidium* removal efficiency. Since removal of particulate matter larger than 1 μm by a membrane filtration process occurs primarily via a size exclusion mechanism, the shape and size distribution of the surrogate must be selected such that the surrogate is not removed to a greater extent than the target organism. Surrogates that have been successfully used in challenge studies include polystyrene microspheres and bacterial endospores. The bacterial endospore, Bacillus subtilis, has been used as a surrogate for *Cryptosporidium* oocysts during challenge studies evaluating pathogen removal by physical treatment processes, including membrane filtration (Rice *et al.* 1996, Fox *et al.* 1998, Trimboli *et al.* 1999, Owen et al, 1999). Studies evaluating cartridge filters have demonstrated that polystyrene microspheres can provide an accurate or conservative measure of removal efficiency (Long, 1983, Li *et al.* 1997). Furthermore, the National Sanitation Foundation (NSF) Environmental Technology Verification (ETV) protocol for verification testing for physical removal of microbiological and particulate contaminants specifies the use of polymeric microspheres of a known size distribution (NSF 2002b). Guidance on selection of an appropriate surrogate for establishing a removal efficiency for *Cryptosporidium* during challenge testing is presented in the Membrane Filtration Guidance Manual (USEPA 2003e).

The design of the proposed challenge studies is similar to the design of the seeding studies described in the literature cited earlier. Seeding studies are used to challenge the membrane module with pathogen levels orders of magnitude higher than those encountered in natural waters. However, elevated feed concentrations can lead to artificially high estimates of removal efficiency. To address this issue, the feed concentration applied to the membrane during challenge studies is capped at a level that will allow the demonstration of up to 6.5 log removal efficiency if the challenge particulate is removed to the detection level.

Because challenge testing with *Cryptosporidium* or a surrogate is not conducted on every membrane module, it is necessary to establish criteria for a non-destructive performance test that can be applied to all production membrane modules. Results from a non-destructive test, such as a bubble point test, that are correlated with the results of challenge testing can be used to establish a quality control release value (QCRV) that is indicative of the ability of a membrane filtration process to remove *Cryptosporidium*. The non-destructive test and QCRV can be used to verify the *Cryptosporidium* removal capability of modules that are not challenge tested. Most membrane manufacturers have already adapted some form of non-destructive testing for product quality control purposes and have established a quality control release value that is indicative of an acceptable product. It may be possible to apply these existing practices for the purpose of verifying the capability of a membrane filtration process to remove *Cryptosporidium*.

Challenge testing provides a means of demonstrating the removal efficiency of an integral membrane module; however, defects or leaks in the membrane or other system components can result in contamination of the filtrate unless they are identified, isolated, and repaired. In order to verify continued performance of a membrane system, today's proposal requires direct integrity testing of membrane filtration processes used to meet *Cryptosporidium* treatment requirements. Direct integrity testing is required because it is a test applied to the physical membrane module and, thus, a direct evaluation of integrity. Furthermore, direct integrity methods are the most sensitive integrity monitoring methods commonly used at the time of this proposal (Adham *et al.* 1995).

The most common direct integrity tests apply a pressure or a vacuum to one side of a fully wetted membrane and monitor either the pressure decay or the volume of displaced fluid over time. However, the proprietary nature of these systems makes it impractical to define a single direct integrity test methodology that is applicable to all existing and future membrane products. Therefore, performance criteria have been established for any direct integrity test methodology used to verify the removal efficiency of a membrane system. These performance criteria are resolution, sensitivity, and frequency.

As stated previously, the resolution of an integrity test refers to the smallest leak that contributes to the response from an integrity test. For example, in a pressure decay integrity test, resolution is the smallest leak that contributes to pressure loss during the test. Today's proposal specifies a resolution of 3 μm or less, which is based on the size of *Cryptosporidium* oocysts. This requirement ensures that a leak that could pass a *Cryptosporidium* oocyst would contribute to the response from an integrity test.

The sensitivity of an integrity test refers to the maximum log removal that can be reliably verified by the test. Again using the pressure decay integrity test as an example, the method sensitivity is a function of the smallest pressure loss that can be detected over a membrane unit. Today's proposal limits the log removal credit that a membrane filtration process is eligible to receive to the maximum log removal value that can be verified by a direct integrity test.

In order to serve as a useful process monitoring tool for assuring system integrity, it is necessary to establish a site-specific control limit for the integrity test that corresponds to the log removal awarded to the process. A general approach for establishing this control limit for some integrity test methods is presented in guidance; however, the utility will need to work with the membrane manufacturer and State to establish a site-specific control limit appropriate for the integrity test used and level of credit awarded. Excursions above this limit indicate a potential integrity breach and would trigger removal of the suspect unit from service followed by diagnostic testing and subsequent repair, as necessary.

Most direct integrity tests available at the time of this proposal must be applied periodically since it is necessary to take the membrane unit out of service to conduct the test. Today's proposal establishes the minimum frequency for performing a direct integrity test at once per 24 hours. Currently, there is no standard frequency for direct integrity testing that has been adopted by all States and membrane treatment facilities. In a recent survey, the required frequency of integrity testing was found to vary from once every four hours to once per week; however, the most common frequency for conducting a direct integrity test was once every 24 hours (USEPA 2001h). Specifically, 10 out of 14 States that require periodic direct integrity testing specify a frequency of once every 24 hours. Furthermore, many membrane manufacturers of systems with automated integrity test systems set up the membrane units to automatically perform a direct integrity test once per 24 hours. EPA has concluded that the 24 hour direct integrity test frequency ensures that removal efficiency is verified on a routine basis without resulting in excessive system downtime.

Since most direct integrity tests are applied periodically, it is necessary to implement some level of continuous monitoring to assess process performance between direct integrity test events. In the absence of a continuous direct integrity test, continuous indirect integrity monitoring is required. Although it has been shown that commonly used indirect integrity monitoring methods lack the sensitivity to detect small integrity breaches that are of concern (Adham *et al.* 1995), they can detect large breaches and provide some assurance that a major failure has not occurred between direct integrity test events. Turbidity monitoring is proposed as the method of indirect integrity monitoring unless the State approves an alternate approach. Available data indicate that an integral membrane filtration process can consistently produce water with a turbidity less than 0.10 NTU, regardless of the feedwater quality. Consequently, EPA is proposing that exceedance of a filtrate turbidity value of 0.15 NTU triggers direct integrity testing to verify and isolate the integrity breach.

c. *Request for comment.* EPA requests comment on the following issues:

- EPA is proposing to include membrane cartridge filters that can be direct integrity tested under the definition of a membrane filtration process since one of the key differences between membrane filtration processes and bag and cartridge filters, within the context of this regulation, is the applicability of direct integrity test methods to the filtration process. EPA requests comment on the inclusion of membrane cartridge filters that can be direct integrity tested under the definition of a membrane filtration process in this rule.
- The applicability of the proposed *Cryptosporidium* removal credits and performance criteria to *Giardia lamblia*.
- Appropriate surrogates, or the characteristics of appropriate surrogates, for use in challenge testing. EPA requests data or information demonstrating the correlation between removal of a proposed surrogate and removal of *Cryptosporidium* oocysts.
- The use of a non-destructive performance test and associated quality control release values for demonstrating the *Cryptosporidium* removal capability of membrane modules that are not directly challenge tested.
- The appropriateness of the minimum direct integrity test frequency of once per 24 hours.
- The proposed minimum reporting frequency for direct integrity testing results above the control limit and indirect integrity monitoring results that trigger direct integrity monitoring.

12. Bag and Cartridge Filtration

a. *What is EPA proposing today?* EPA is proposing criteria for awarding *Cryptosporidium* removal credit of 1 log for bag filtration processes and 2 log for cartridge filtration processes. To receive removal credit the process must: (1) Meet the basic definition of a bag or cartridge filter and (2) have removal efficiency established through challenge testing.

Definition of a Bag or Cartridge Filter

For the purpose of this rule, bag and cartridge filters are defined as pressure driven separation processes that remove particulate matter larger than 1 μm using an engineered porous filtration media through either surface or depth filtration.

The distinction between bag filters and cartridge filters is based on the type of filtration media used and the manner in which the devices are constructed. Bag filters are typically constructed of a non-rigid, fabric filtration media housed in a pressure vessel in which the direction of flow is from the inside of the bag to outside. Cartridge filters are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in pressure vessels in which flow is from the outside of the cartridge to the inside.

Although all filters classified as cartridge filters share similarities with respect to their construction, there are significant differences among the various commercial cartridge filtration devices. From a public health perspective, an important distinction among these filters is the ability to directly test the integrity of the filtration system in order to verify that there are no leaks that could result in contamination of the filtrate. Any membrane cartridge filtration device that can be direct integrity tested according to the criteria specified in section IV.C.11.a is eligible for removal credit as a membrane, subject to the criteria specified in that section. Section IV.C.12 applies to all bag filters, as well as to cartridge filters which cannot be direct integrity tested.

Challenge Testing

In order to receive 1 log removal credit, a bag filter must have a demonstrated removal efficiency of 2 log or greater for *Cryptosporidium*. Similarly, to receive 2 log removal credit, a cartridge filter must have a demonstrated removal efficiency of 3 log or greater for *Cryptosporidium*. The 1 log factor of safety is applied to the removal credit awarded to these filtration devices based on two primary considerations. First, the removal efficiency of some bag and cartridge filters has been observed to vary by more than 1 log over the course of operation (Li *et al.* 1997, NSF 2001a, NSF 2001b). Second, bag and cartridge filters are not routinely direct integrity tested during operation in the field; hence, there is no means of verifying the removal efficiency of filtration units during routine use. Based on these considerations, a conservative approach to awarding removal credit based on challenge test results is warranted.

Removal efficiency must be demonstrated through a challenge test conducted on the bag or cartridge filter proposed for use in full-scale drinking water treatment facilities for removal of *Cryptosporidium*. Challenge testing is required for specific products and is not intended to be site specific. At the discretion of the State, data from challenge studies conducted prior to promulgation of this regulation may be considered in lieu of additional testing. However, the prior testing must have been conducted in a manner that demonstrates a removal efficiency for *Cryptosporidium* commensurate with the treatment credit awarded to the process. Guidance on conducting challenge studies to demonstrate the *Cryptosporidium* removal efficiency of filtration units is presented in the Membrane Filtration Guidance Manual (USEPA 2003e). Challenge testing must

be conducted according to the following criteria:

- Challenge testing must be conducted on a full-scale filter element identical in material and construction to the filter elements proposed for use in full-scale treatment facilities.
- Challenge testing must be conducted using *Cryptosporidium* oocysts or a surrogate which is removed no more efficiently than *Cryptosporidium* oocysts. The organism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate must be determined using a method capable of discretely quantifying the specific organism or surrogate used in the test, *i.e.*, gross water quality measurements such as turbidity cannot be used.
- The maximum allowable feed water concentration used during a challenge test is based on the detection limit of the challenge particulate in the filtrate and calculated using one of the following equations.

For bag filters:

$$\text{Maximum Feed Concentration} = 3.16 \times 10^3 \times (\text{Filtrate Detection Limit})$$

For cartridge filters:

$$\text{Maximum Feed Concentration} = 3.16 \times 10^4 \times (\text{Filtrate Detection Limit})$$

This will allow the demonstration of up to 3.5 log removal for bag filters and 4.5 log removal for cartridge filters during challenge testing if the challenge particulate is removed to the detection limit.

- Challenge testing must be conducted at the maximum design flow rate specified by the manufacturer.
- Each filter must be tested for a duration sufficient to reach 100% of the terminal pressure drop, a parameter specified by the manufacturer which establishes the end of the useful life of the filter. In order to achieve terminal pressure drop during the test, it will be necessary to add particulate matter to the test solution, such as fine carbon test dust or bentonite clay particles.
- Each filter must be challenged with the challenge particulate during three periods over the filtration cycle: within 2 hours of start-up after a new bag or cartridge filter has been installed, when the pressure drop is between 45 and 55% of the terminal pressure drop, and at the end of the run after the pressure drop has reached 100% of the terminal pressure drop.
- Removal efficiency of a bag or cartridge filtration process is determined from the results of the challenge test, and expressed in terms of log removal values as defined by the following equation:

$$LRV = LOG_{10}(C_f) - LOG_{10}(C_p)$$

where LRV = log removal value demonstrated during challenge testing; C_f = the feed concentration used during the challenge test; and C_p = the filtrate concentration observed during the challenge test. For this equation to be valid, equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, then the term C_p is set equal to the detection limit. An LRV is calculated for each filter evaluated during the test.

- In order to receive treatment credit for *Cryptosporidium* under this proposed rule, challenge testing must demonstrate a removal efficiency of 2 log or greater for bag filtration and 3 log or greater for cartridge filtration. If fewer than twenty filters are tested, then removal efficiency of the process is set equal to the lowest of the representative LRVs among the various filters tested. If twenty or more filters are tested, then removal efficiency of the process is set equal to the 10th percentile of the representative LRVs among the various filters tested. The percentile is defined by [i/(n+1)] where i is the rank of n individual data points ordered lowest to highest. It may be necessary to calculate the 10th percentile using linear interpolation.
- Any significant modification to the filtration unit (*e.g.,* changes to the filtration media, changes to the configuration of the filtration media, significant modifications to the sealing system) would require additional challenge testing to demonstrate removal efficiency of the modified unit.

b. *How was this proposal developed?* The Stage 2 M–DBP Agreement in Principle recommended that EPA develop criteria for awarding *Cryptosporidium* removal credits of 1 log for bag filters and 2 log for cartridge filters. Today's proposal is consistent with the Agreement.

A limited amount of published data are available regarding the removal efficiency of bag and cartridge filters with respect to *Cryptosporidium* oocysts or suitable surrogates. The relevant studies identified in the literature are summarized in Table IV–18.

TABLE IV–18.—RESULTS FROM STUDIES OF *Cryptosporidium* OR SURROGATE REMOVAL BY BAG AND CARTRIDGE FILTERS

Process	Log removal	Organism/surrogate	Reference
Bag and cartridge filtration in series.	1.1 to 2.1	3 to 6 μm spheres	NSF 2001a.
Cartridge filtration	3.5 (average)	*Cryptosporidium*	Enriquez et al. 1999.
Cartridge filtration	3.3 (average)	*Cryptosporidium*	Roessler, 1998.
Cartridge filtration	1.1 to 3.3	*Cryptosporidium*	Schaub et al. 1993.
Cartridge filtration	0.5 to 3.6	5.7 μm spheres	Long, 1983.
Cartridge filtration	2.3 to 2.8	*Cryptosporidium*	Ciardelli, 1996a.
Cartridge filtration	2.7 to 3.7	*Cryptosporidium*	Ciardelli, 1996b.
Prefilter and bag filter in series	1.9 to 3.2	3.7 μm spheres	NSF 2001b.
Bag filtration	~3.0	*Cryptosporidium*	Cornwell and LeChevallier, 2002.
Bag filtration	0.5 to 3.6	*Cryptosporidium*	Li et al. 1997.
Bag filtration	0.5 to 2.0	4.5 μm spheres	Goodrich et al. 1995.

These data demonstrate highly variable removal performance for these processes, ranging from 0.5 log to 3.6 log for both bag and cartridge filtration. Results of these studies also show no correlation between the pore size rating established by the manufacturer and the removal efficiency of a filtration device. In a study evaluating two cartridge filters, both with a pore size rating of 3 μm, a 2 log difference in *Cryptosporidium* oocyst removal was observed between the two filters (Schaub *et al.* 1993). Another study evaluated seventeen cartridge filters with a range of pore size ratings from 1 μm to 10 μm and found no correlation with removal efficiency (Long, 1983). Li *et al.* (1997) evaluated three bag filters with similar pore size ratings and observed a 3 log difference in

Cryptosporidium oocyst removal among them. These results indicate that bag and cartridge filters may be capable of achieving removal of oocysts in excess of 3 log; however, performance can vary significantly among products and there appears to be no correlation between pore size rating and removal efficiency.

Based on available data, specific design criteria that correlate to removal efficiency cannot be derived for bag and cartridge filters. Furthermore, the removal efficiency of these proprietary devices can be impacted by product variability, increasing pressure drop over the filtration cycle, flow rate, and other operating conditions. The data in Table IV–18 were generated from studies performed under a variety of operating conditions, many of which could not be considered conservative (or worst-case) operation. These considerations lead to the proposed challenge testing requirements which are intended to establish a product-specific removal efficiency.

The proposed challenge testing is product-specific and not site-specific since the intent of this testing is to demonstrate the removal capabilities of the filtration device rather than evaluate the feasibility of implementing the technology at a specific plant. Challenge testing must be conducted using full-scale filter elements in order to evaluate the performance of the entire unit, including the filtration media, seals, filter housing and other components integral to the filtration system. This will improve the applicability of challenge test results to full-scale performance. Multiple filters of the same type can be tested to provide a better statistical basis for estimating removal efficiency.

Either *Cryptosporidium* oocysts or a suitable surrogate could be used as the challenge particulate during the test. Challenge testing with *Cryptosporidium* provides direct verification of removal efficiency; however, some studies have demonstrated that surrogates, such as polystyrene microspheres, can provide an accurate or conservative measure of removal efficiency (Long 1983, Li *et al.* 1997). Furthermore, the National Sanitation Foundation (NSF) Environmental Technology Verification (ETV) protocol for verification testing for physical removal of microbiological and particulate contaminants specifies the use of polymeric microspheres of a known size distribution (NSF 2002b). Guidance on selection of an appropriate surrogate for establishing a removal efficiency for *Cryptosporidium* during challenge testing is presented in the Membrane Filtration Guidance Manual (USEPA 2003e).

In order to demonstrate a removal efficiency of at least 2 or 3 log for bag or cartridge filters, respectively, it will likely be necessary to seed the challenge particulate into the test solution. A criticism of published studies that use this approach is that the seeded levels are orders of magnitude higher than those encountered in natural waters and this could potentially lead to artificially high estimates of removal efficiency. To address this issue, the feed concentration applied to the filter during challenge studies is capped at a level that will allow the demonstration of a removal efficiency up to 4.5 log for cartridge filters and 3.5 log for bag filters if the challenge particulate is removed to the detection level.

The removal efficiency of some bag and cartridge filtration devices has been shown to decrease over the course of a filtration cycle due to the accumulation of solids and resulting increase in pressure drop. As an example, Li *et al.* (1997) observed that the removal of 4.5 μm microspheres by a bag filter decreased from 3.4 log to 1.3 log over the course of a filtration cycle. Studies evaluating bag and cartridge filtration under the NSF ETV program have also shown a degradation in removal efficiency over the course of the filtration cycle (NSF 2001a and 2001b). In order to evaluate this potential variability, the challenge studies are designed to assess removal efficiency during three periods of a filtration cycle: within two hours of startup following installation of a new filter, between 45% and 55% of terminal pressure drop, and at the end of the run after 100% of terminal pressure drop is realized.

Although challenge testing can provide an estimate of removal efficiency for a bag or cartridge filtration process, it is not feasible to conduct a challenge test on every production filter. This, coupled with variability within a product line, could result in some production filters that do not meet the removal efficiency demonstrated during challenge testing. For membrane filtration processes, this problem is addressed through the use of a quality control release value established for a non-destructive test, such as a bubble point test or pressure hold test, that is correlated to removal efficiency. Since the non-destructive test can be applied to all production membrane modules, this provides a feasible means of verifying the performance of every membrane module used by a PWS. However, the non-destructive tests applied to membrane filtration processes cannot be applied to most bag and cartridge filtration devices, and EPA is not aware of an alternative non-destructive test that can be used with these devices.

Typical process monitoring for bag and cartridge filtration systems includes turbidity and pressure drop to determine when filters must be replaced. However, the applicability of either of these process monitoring parameters as tools for verifying removal of *Cryptosporidium* has not been demonstrated. Only a few bag or cartridge filtration studies have attempted to correlate turbidity removal with removal of *Cryptosporidium* oocysts or surrogates. Li *et al.* (1997) found that the removal efficiency for turbidity was consistently lower than removal efficiency for oocysts or microspheres for the three bag filters evaluated. Furthermore, none of the filters was capable of consistently producing a filtered water turbidity below 0.3 NTU for the waters evaluated. The contribution to turbidity from particles much smaller than *Cryptosporidium* oocysts, and much smaller than the mesh size of the filter, make it difficult to correlate removal of turbidity with removal of *Cryptosporidium*. Consequently, EPA is proposing a 1 log factor of safety to be applied to challenge test results in awarding treatment credit to bag and cartridge filters, and is not proposing integrity monitoring requirements for these devices.

c. *Request for comment.* EPA requests comment on the following issues concerning bag and cartridge filters:

- The performance of bag and cartridge filters in removing *Cryptosporidium* through all differential pressure ranges in a filter run—EPA requests laboratory and field data, along with associated quality assurance and quality control information, that will support a determination of the appropriate level of *Cryptosporidium* removal credit to award to these technologies.
- The performance of bag and cartridge filters in removing *Cryptosporidium* when used in series with other bag or cartridge filters—EPA requests laboratory and field data, along with associated quality assurance and quality control information, that will support a determination of the appropriate level of *Cryptosporidium* removal credit to award to these technologies when used in series.
- Appropriate surrogates, or the characteristics of appropriate surrogates, for use in challenge testing bag and cartridge filters—EPA requests data or information demonstrating the correlation between removal of a proposed surrogate and removal of *Cryptosporidium* oocysts.

• The availability of non-destructive tests that can be applied to bag and cartridge filters to verify the removal efficiency of production filters that are not directly challenge tested—EPA requests data or information demonstrating the correlation between a proposed non-destructive test and the removal of *Cryptosporidium* oocysts.

• The applicability of pressure drop monitoring, filtrate turbidity monitoring, or other process monitoring and process control procedures to verify the integrity of bag and cartridge filters—EPA requests data or information demonstrating the correlation between a proposed process monitoring tool and the removal of *Cryptosporidium* oocysts.

• The applicability of bag and cartridge filters to different source water types and treatment scenarios.

• The applicability of the proposed *Cryptosporidium* removal credits and testing criteria to *Giardia lamblia*.

• The use of a 1 log factor of safety for awarding credit to bag and cartridge filters—EPA requests comment on whether this is an appropriate factor of safety to account for the inability to conduct integrity monitoring of these devices, as well as the variability in removal efficiency observed over the course of a filtration cycle for some filtration devices. This inability creates uncertainty regarding both changes in the performance of a given filter during use and variability in performance among filters in a given product line. If the 1 log factor of safety is higher than necessary to account for these factors, should the Agency establish a lower value, such as a 0.5 log factor of safety?

13. Secondary Filtration

a. *What is EPA proposing today?* Today's proposal allows systems using a second filtration stage to receive an additional 0.5 log *Cryptosporidium* removal credit. To be eligible for this credit, the secondary filtration must consist of rapid sand, dual media, granular activated carbon (GAC), or other fine grain media in a separate stage following rapid sand or dual media filtration. A cap, such as GAC, on a single stage of filtration will not qualify for this credit. In addition, the first stage of filtration must be preceded by a coagulation step, and both stages must treat 100% of the flow.

b. *How was this proposal developed?* Although not addressed in the Agreement in Principle, EPA has determined that secondary filtration meeting the criteria described in this section will achieve additional removal of *Cryptosporidium* oocysts. Consequently, additional removal credit may be appropriate. As reported in section III.D, many studies have shown that rapid sand filtration preceded by coagulation can achieve significant removal of *Cryptosporidium* (Patania *et al.* 1995, Nieminski and Ongerth 1995, Ongerth and Pecoraro 1995, LeChevallier and Norton 1992, LeChevallier *et al.* 1991, Dugan *et al.* 2001, Nieminski and Bellamy 2000, McTigue *et al.* 1998, Patania *et al.* 1999, Huck *et al.* 2000, Emelko *et al.* 2000). While these studies evaluated only a single stage of filtration, the same mechanisms of removal are expected to occur in a second stage of granular media filtration.

EPA received data from the City of Cincinnati, OH, on the removal of aerobic spores through a conventional treatment facility that employs GAC contactors for DBP, taste, and odor control after rapid sand filtration. As described previously, a number of studies (Dugan *et al.* 2001, Emelko *et al.* 1999 and 2000, Yates *et al.* 1998, Mazounie *et al.* 2000) have demonstrated that aerobic spores are a conservative indicator of *Cryptosporidium* removal by granular media filtration when preceded by coagulation.

During the period of 1999 and 2000, the mean values of reported spore concentrations in the influent and effluent of the Cincinnati GAC contactors were 35.7 and 6.4 cfu/100 mL, respectively, indicating an average removal of 0.75 log across the contactors. Approximately 16% of the GAC filtered water results were below detection limit (1 cfu/100 mL) so the actual log spore removal may have been greater than indicated by these results.

In summary, studies in the cited literature demonstrate that a fine granular media filter preceded by coagulation can achieve high levels of *Cryptosporidium* removal. Data on increased removal resulting from a second stage of filtration are limited, and there is uncertainty regarding how effective a second stage of filtration will be in reducing levels of microbial pathogens that are not removed by the first stage of filtration. However, EPA has concluded that a secondary filtration process can achieve 0.5 log or greater removal of *Cryptosporidium* based on (1) the theoretical consideration that the same mechanisms of pathogen removal will be operative in both a primary and secondary filtration stage, and (2) data from the City of Cincinnati showing aerobic spore removal in GAC contactors following rapid sand filtration. Therefore, EPA believes it is appropriate to propose 0.5 log additional *Cryptosporidium* treatment credit for systems using secondary filtration which meets the criteria of this section.

c. *Request for comment.* The Agency requests comment on awarding a 0.5 log *Cryptosporidium* removal credit for systems using secondary filtration, including the design and operational criteria required to receive the log removal credit. EPA specifically requests comment on the following issues:

• Should there be a minimum required depth for the secondary filter (*e.g.*, 24 inches) in order for the system to receive credit?

• Should systems be eligible to receive additional *Cryptosporidium* treatment credit within the microbial toolbox for both a second clarification stage (*e.g.*, secondary filtration, second stage sedimentation) and lower finished water turbidity, given that additional particle removal achieved by the second clarification stage will reduce finished water turbidity?

14. Ozone and Chlorine Dioxide

a. *What is EPA proposing today?* Similar to the methodology used for estimating log inactivation of *Giardia lamblia* by various chemical disinfectants in 40 CFR 141.74, EPA is proposing the CT concept for estimating log inactivation of *Cryptosporidium* by chlorine dioxide or ozone. In today's proposal, systems must determine the total inactivation of *Cryptosporidium* each day the system is in operation, based on the CT values in Table IV–19 for ozone and Table IV–20 for chlorine dioxide. The parameters necessary to determine the total inactivation of *Cryptosporidium* must be monitored as stated in 40 CFR 141.74(b)(3)(i), (iii), and (iv), which is as follows:

• The temperature of the disinfected water must be measured at least once per day at each residual disinfectant concentration sampling point.

• The disinfectant contact time(s) (''T'') must be determined for each day during peak hourly flow.

• The residual disinfectant concentration(s) (''C'') of the water before or at the first customer must be measured each day during peak hourly flow.

Systems may have several disinfection segments (the segment is defined as a treatment unit process with a measurable disinfectant residual level and a liquid volume) in sequence along the treatment train. In determining the total log inactivation, the system may calculate the log inactivation for each disinfection segment and use the sum of the log inactivation estimates of *Cryptosporidium* achieved through the

plant. The Toolbox Guidance Manual, available in draft with today's proposal, provides guidance on methodologies for determining CT values and estimating log inactivation for different disinfection reactor designs and operations.

TABLE IV–19.—CT VALUES FOR *Cryptosporidium* INACTIVATION BY OZONE

Log credit	Water Temperature, °C [1]									
	<=0.5	1	2	3	5	7	10	15	20	25
0.5	12	12	10	9.5	7.9	6.5	4.9	3.1	2.0	1.2
1.0	24	23	21	19	16	13	9.9	6.2	3.9	2.5
1.5	36	35	31	29	24	20	15	9.3	5.9	3.7
2.0	48	46	42	38	32	26	20	12	7.8	4.9
2.5	60	58	52	48	40	33	25	16	9.8	6.2
3.0	72	69	63	57	47	39	30	19	12	7.4

[1] CT values between the indicated temperatures may be determined by interpolation.

TABLE IV–20.—CT VALUES FOR *Cryptosporidium* INACTIVATION BY CHLORINE DIOXIDE

Log credit	Water Temperature, °C [1]									
	<=0.5	1	2	3	5	7	10	15	20	25
0.5	319	305	279	256	214	180	138	89	58	38
1.0	637	610	558	511	429	360	277	179	116	75
1.5	956	915	838	767	643	539	415	268	174	113
2.0	1275	1220	1117	1023	858	719	553	357	232	150
2.5	1594	1525	1396	1278	1072	899	691	447	289	188
3.0	1912	1830	1675	1534	1286	1079	830	536	347	226

[1] CT values between the indicated temperatures may be determined by interpolation.

The system may demonstrate to the State, through the use of a State-approved protocol for on-site disinfection challenge studies or other information satisfactory to the State, that CT values other than those specified in Tables IV–19 or IV–20 are adequate to demonstrate that the system is achieving the required log inactivation of *Cryptosporidium*. Protocols for making such demonstrations are available in the Toolbox Guidance Manual.

b. *How was this proposal developed?* EPA relied in part on analyses by Clark *et al.* (2002a and 2002b) to develop the CT values for ozone and chlorine dioxide inactivation of *Cryptosporidium* in today's proposal. Clark *et al.* (2002a) used data from studies of ozone inactivation of *Cryptosporidium* in laboratory water to develop predictive equations for estimating inactivation (Rennecker *et al.* 1999, Li *et al.* 2001) and data from studies in natural water to validate the equations (Owens *et al.* 2000, Oppenheimer *et al.* 2000). For chlorine dioxide, Clark *et al.* (2002b) employed data from Li *et al.* (2001) to develop equations for predicting inactivation, and used data from Owens *et al.* (1999) and Ruffell *et al.* (2000) to validate the equations.

Another step in developing the CT values for *Cryptosporidium* inactivation in today's proposal involved consideration of the appropriate confidence bound to apply when analyzing the inactivation data. A confidence bound represents a safety margin that accounts for variability and uncertainty in the data that underlie the analysis. Confidence bounds are intended to provide a high likelihood that systems operating at a given CT value will achieve at least the corresponding log inactivation level in the CT table.

Two types of confidence bounds that are used when assessing relationships between variables, such as disinfectant dose (CT) and log inactivation, are confidence in the regression and confidence in the prediction. Confidence in the regression accounts for uncertainty in the regression line (*e.g.*, a linear relationship between temperature and the log of the ratio of CT to log inactivation). Confidence in the prediction accounts for both uncertainty in the regression line and variability in experimental observations—it describes the likelihood of a single future data point falling within a range. Bounds for confidence in prediction are wider (*i.e.*, more conservative) than those for confidence in the regression. Depending on the degree of confidence applied, most points in a data set typically will fall within the bounds for confidence in the prediction, while a significant fraction will fall outside the bounds for confidence in the regression.

In developing earlier CT tables, EPA has used bounds for confidence in the prediction. This was a conservative approach that was taken with consideration of the limited inactivation data that were available and that reasonably ensured systems would achieve the required inactivation level. The November 2001 draft of the LT2ESWTR included CT tables for *Cryptosporidium* inactivation by ozone and chlorine dioxide that were derived using confidence in prediction (USEPA 2001g). However, based on comments received on those draft tables, along with further analyses described next, EPA has revised this approach in today's proposal.

The underlying *Cryptosporidium* inactivation data used to develop the CT tables exhibit significant variability. This variability is due to both experimental error and potential true variability in the inactivation rate. Experimental error is associated with the assays used to measure loss of infectivity, measurement of the disinfectant concentration, differences in technique among researchers, and other factors. True variability in the inactivation rate would be associated with variability in resistance to the disinfectant between different populations of oocysts and variability in the effect of water matrix on the inactivation process.

In considering the appropriate confidence bounds to use for developing the CT tables in today's proposal, EPA was primarily concerned with accounting for uncertainty in the regression and for true variability in the inactivation rate. Variability associated with experimental error was a lessor concern, as the purpose of the CT tables is to ensure a given level of inactivation and not predict the measured result of an individual experiment.

Because confidence in the prediction accounts for all variability in the data sets (both true variability and experimental error), it may provide a higher margin of safety than is necessary. Nevertheless, in other disinfection applications, the use of confidence in the prediction may be appropriate, given limited data sets and uncertainty in the source of the variability. However, the high doses of ozone and chlorine dioxide that are needed to inactivate *Cryptosporidium* create an offsetting concern with the formation of DBPs (*e.g.*, bromate and chlorite). In consideration of these factors and the statutory provision for balancing risks among contaminants, EPA attempted to exclude experimental error from the confidence bound when developing the CT tables in today's proposal (*i.e.*, used a less conservative approach than confidence in the prediction).

In order to select confidence bounds reflecting potential true variability between different oocyst populations (lots) but not variability due to measurement and experimental imprecision, it was necessary to estimate the relative contributions of these variance components. This was done by first separating inactivation data points into groups having the same *Cryptosporidium* oocyst lot and experimental conditions (*e.g.*, water matrix, pH, temperature). Next, the variance within each group was determined. It was assumed that this within-group variance could be attributed entirely to experimental error, as neither of the factors expected to account for true variability in the inactivation rate (*i.e.*, oocyst lot or water matrix) changed within a group. Finally, comparing the average within-group variance to the total variance in a data set provided an indication of the fraction of total variance that was due to experimental error (see Sivaganesan 2003 and Messner 2003 for details).

In carrying out this analysis on the Li *et al.* (2001) and Rennecker *et al.* (1999) data sets for ozone inactivation of *Cryptosporidium*, EPA estimated that 87.5% of the total variance could be attributed to experimental error (Sivaganesan 2003). A similar analysis done by Najm *et al.* (2002) on the Oppenheimer *et al.* (2000) data set for ozone produced an estimate of 89% of the total variance due to experimental error. For chlorine dioxide inactivation of *Cryptosporidium*, EPA estimated that 62% of the total variance in the Li *et al.* (2001) and Ruffle *et al.* (1999) data sets could be attributed to experimental error (Messner 2003). The different fractions attributed to experimental error between the chlorine dioxide and ozone data sets presumably relates to the use of different experimental techniques (*e.g.*, infectivity assays).

EPA employed estimates of the fraction of variance not attributable to experimental error (12.5% for ozone and 38% for chlorine dioxide) in a modified form of the equation used to calculate a bound for confidence in prediction (Messner 2003). These were applied to the regression equations developed by Clark *et al.* (2002a and 2002b) in order to estimate CT values for an upper 90% confidence bound (Sivaganesan 2003, Messner 2003). These are the CT values shown in Tables IV–19 and IV–20 for ozone and chlorine dioxide, respectively.

Since the available data are not sufficient to support the CT calculation for an inactivation level greater than 3 log, the use of Tables IV–19 and IV–20 is limited to inactivation less than or equal to 3 log. In addition, the temperature limitation for these tables is 1 to 25 °C. If the water temperature is higher than 25 °C, temperature should be set to 25 °C for the log inactivation calculation.

EPA recognizes that inactivation rates may be sensitive to water quality and operational conditions in the plant. To reflect this potential, systems are given the option to perform a site specific inactivation study to determine CT requirements. The State must approve the protocols or other information used to derive alternative CT values. However, EPA has provided guidance for systems in making such demonstrations in the Toolbox Guidance Manual.

During meetings of the Stage 2 M-DBP Advisory Committee, CT values were used in the model for impact analysis of different regulatory options (the model Surface Water Analytical Tool (SWAT), as described in Economic Analysis for the LT2ESWTR, USEPA 2003a). Those preliminary CT values were based on a subset of the data from the Li *et al.* (2001) study with laboratory waters and were adjusted with a factor to match the mean CT values derived from the Oppenheimer *et al.* (2000) study with natural waters. In comparison, the CT values in today's proposal are higher. However, the current CT values are based on larger data sets and more comprehensive analyses. Consequently, they provide more confidence in estimates of *Cryptosporidium* log inactivation than the preliminary estimates used in earlier SWAT modeling. EPA has subsequently re-run analyses for LT2ESWTR impact assessments with the updated CT values (USEPA 2003a).

c. *Request for comments.* EPA requests comment on the proposed approach to awarding credit for inactivation of *Cryptosporidium* by chlorine dioxide and ozone, including the following specific issues:

- Determination of CT and the confidence bounds used for estimating log inactivation of *Cryptosporidium*;
- The ability of systems to apply these CT tables in consideration of the MCLs for bromate and chlorite; and
- Any additional data that may be used to confirm or refine the proposed CT tables.

15. Ultraviolet Light

a. *What is EPA proposing today?* EPA is proposing criteria for awarding credit to ultraviolet (UV) disinfection processes for inactivation of *Cryptosporidium*, *Giardia lamblia*, and viruses. The inactivation credit a system can receive for each target pathogen is based on the UV dose applied by the system in relation to the UV dose requirements in this section (see Table IV–21).

To receive UV disinfection credit, a system must demonstrate a UV dose using the results of a UV reactor validation test and ongoing monitoring. The reactor validation test establishes the operating conditions under which a reactor can deliver a required UV dose. Monitoring is used to demonstrate that the system maintains these validated operating conditions during routine use.

UV dose (fluence) is defined as the product of the UV intensity over a surface area (fluence rate) and the exposure time. In practice, UV reactors deliver a distribution of doses due to variation in light intensity and flow path as particles pass through the reactor. However, for the purpose of determining compliance with the dose requirements in Table IV–21, UV dose must be assigned to a reactor based on the degree of inactivation of a microorganism achieved during a reactor validation test. This assigned UV dose is determined through comparing the reactor validation test results with a known dose-response relationship for the test microorganism. The State may

designate an alternative basis for awarding UV disinfection credit.

EPA is developing the UV Disinfection Guidance Manual (USEPA 2003d) to assist systems and States with implementing UV disinfection, including validation testing of UV reactors. This guidance is available in draft in the docket for today's proposal (*http://www.epa.gov/edocket/*).

UV Dose Tables

Table IV–21 shows the UV doses that systems must apply to receive credit for up to 3 log inactivation of *Cryptosporidium* and *Giardia lamblia* and up to 4 log inactivation of viruses. These dose values are for UV light at a wavelength of 254 nm as delivered by a low pressure mercury vapor lamp. However, the dose values can be applied to other UV lamp types (*e.g.*, medium pressure mercury vapor lamps) through reactor validation testing, such as is described in the draft UV Disinfection Guidance Manual (USEPA 2003d). In addition, the dose values in Table IV–21 are intended for post-filter application of UV in filtration plants and for systems that meet the filtration avoidance criteria in 40 CFR 141.71.

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Table IV-21.-- UV Dose Requirements for *Cryptosporidium*, *Giardia lamblia*, and Virus Inactivation Credit

Log credit	*Cryptosporidium* UV dose (mJ/cm^2)	*Giardia lamblia* UV dose (mJ/cm^2)	Virus UV dose (mJ/cm^2)
0.5	1.6	1.5	39
1.0	2.5	2.1	58
1.5	3.9	3.0	79
2.0	5.8	5.2	100
2.5	8.5	7.7	121
3.0	12	11	143
3.5	NA	NA	163
4.0	NA	NA	186

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Reactor Validation Testing

For a system to receive UV disinfection credit, the UV reactor type used by the system must undergo validation testing to demonstrate the operating conditions under which the reactor can deliver the required UV dose. Unless the State approves an alternative approach, this testing must involve the following: (1) Full scale testing of a reactor that conforms uniformly to the UV reactors used by the system and (2) inactivation of a test microorganism whose dose response characteristics have been quantified with a low pressure mercury vapor lamp.

Validation testing must determine a set of operating conditions that can be monitored by the system to ensure that the required UV dose is delivered under the range of operating conditions applicable to the system. At a minimum, these operating conditions must include flow rate, UV intensity as measured by a UV sensor, and UV lamp status. The validated operating conditions determined by testing must account for the following factors: (1) UV absorbance of the water, (2) lamp fouling and aging, (3) measurement uncertainty of on-line sensors, (4) dose distributions arising from the velocity profiles through the reactor, (5) failure of UV lamps or other critical system components, and (6) inlet and outlet piping or channel configurations of the UV reactor. In the draft UV Disinfection Guidance Manual (USEPA 2003d), EPA describes testing protocols for reactor validation that are intended to meet these criteria.

Reactor Monitoring

Systems must monitor for parameters necessary to demonstrate compliance with the operating conditions that were validated for the required UV dose. At a minimum systems must monitor for UV intensity as measured by a UV sensor, flow rate, and lamp outage. As part of this, systems must check the calibration of UV sensors and recalibrate in accordance with a protocol approved by the State.

b. *How was this proposal developed?* UV disinfection is a physical process relying on the transference of electromagnetic energy from a source (lamp) to an organism's cellular material (USEPA 1986). In the Stage 2 M–DBP Agreement in Principle, the Advisory Committee recommended that EPA determine the UV doses needed to achieve up to 3 log inactivation of *Giardia lamblia* and *Cryptosporidium* and up to 4 log inactivation of viruses.

The Agreement further recommends that EPA develop standards to determine if UV systems are acceptable for compliance with drinking water disinfection requirements, including (1) a validation protocol for drinking water applications of UV technology and (2) on-site monitoring requirements to ensure ongoing compliance with UV dose tables. EPA also agreed to develop a UV guidance manual to facilitate design and operation of UV installations. Today's proposal and

accompanying guidance for UV are consistent with the Agreement.

UV Dose Tables

The UV dose values in Table IV–21 are based on meta-analyses of UV inactivation studies with *Cryptosporidium parvum*, *Giardia lamblia*, *Giardia muris*, and adenovirus (Qian *et al.* 2003, USEPA 2003d). Proposed UV doses for inactivation of viruses are based on the dose-response of adenovirus because, among viruses that have been studied, it appears to be the most UV resistant and is a widespread waterborne pathogen (health effects of adenovirus are described in Embrey 1999).

The data supporting the dose values in Table IV–21 are from bench-scale studies using low pressure mercury vapor lamps. These data were chosen because the experimental conditions allow UV dose to be accurately quantified. Low pressure lamps emit light primarily at a single wavelength (254 nm) within the germicidal range of 200–300 nm. However, as noted earlier, these dose tables can be applied to reactors with other lamp types through reactor challenge testing, as described in the draft guidance manual. Bench scale studies are preferable for determining pathogen dose-response characteristics, due to the uniform dose distribution.

The data sets and statistical evaluation that were used to develop the UV dose table for *Cryptosporidium*, *Giardia lamblia*, and viruses are described in the draft UV Disinfection Guidance Manual (USEPA 2003d) and Qian *et al.* 2003.

Reactor Validation Testing

Today's proposal requires testing of full-scale UV reactors because of the difficulty in predicting reactor disinfection performance based on modeled results or on the results of testing at a reduced scale. All flow-through UV reactors deliver a distribution of doses due to variation in light intensity within the reactor and the different flow paths of particles passing through the reactor. Moreover, the reactor dose distribution varies temporally due to processes like lamp aging and fouling, changes in UV absorbance of the water, and fluctuations in flow rate. Consequently, it is more reliable to evaluate reactor performance through a full scale test under conditions that can be characterized as ''worst case'' for a given application. Such conditions include maximum and minimum flow rate and reduced light intensity within the reactor that accounts for lamp aging, fouling, and UV absorbance of the water. Protocols for reactor validation testing are presented in the draft UV guidance manual.

c. *Request for comment.* The Agency requests comment on whether the criteria described in this section for awarding treatment credit for UV disinfection are appropriate, and whether additional criteria, or more specific criteria, should be included.

16. Individual Filter Performance

a. *What is EPA proposing today?* EPA is proposing an additional 1.0 log *Cryptosporidium* treatment credit for systems that achieve individual filter performance consistent with the goals established for the Partnership for Safe Water Phase IV in August 2001 (AWWA *et al.* 2001). Specifically, systems must demonstrate ongoing compliance with the following turbidity criteria, based on continuous monitoring of turbidity for each individual filter as required under 40 CFR 141.174 or 141.560, as applicable:

(1) Filtered water turbidity less than 0.1 NTU in at least 95% of the maximum daily values recorded at each filter in each month, excluding the 15 minute period following backwashes, and

(2) No individual filter with a measured turbidity level of greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.

Note that today's proposal does not include a required peer review step as a condition for receiving additional credit. Rather, EPA is proposing to award additional credit to systems that meet the performance goals of a peer review program (Phase IV). Systems that receive the 1 log additional treatment credit for individual filter performance, as described in this section, cannot also receive an additional 0.5 log additional credit for lower finished water turbidity as described in section IV.C.8.

b. *How was this proposal developed?* In the Stage 2 M–DBP Agreement in Principle, the Advisory Committee recommended a peer review program as a microbial toolbox component that should receive a 1.0 log *Cryptosporidium* treatment credit. The Committee specified Phase IV of the Partnership for Safe Water (Partnership) as an example of the type of peer review program where a 1.0 log credit would be appropriate.

The Partnership is a voluntary cooperative program involving EPA, the Association of Metropolitan Water Agencies (AMWA), the American Water Works Association (AWWA), the National Association of Water Companies (NAWC), the Association of State Drinking Water Administrators (ASDWA), the American Water Works Association Research Foundation (AWWARF), and surface water utilities throughout the United States. The intent of the Partnership is to increase protection against microbial contaminants by optimizing treatment plant performance.

At the time of the Advisory Committee recommendation, Phase IV was under development by the Partnership. It was to be based on Composite Correction Program (CCP) (USEPA 1991) procedures and performance goals, and was to be awarded based on an on-site evaluation by a third-party team. The performance goals for Phase IV were such that, over a year, each sedimentation basin and each filter would need to produce specified turbidity levels based on the maximum of all the values recorded during the day. Sedimentation performance goals were set at 2.0 NTU if the raw water was greater than 10 NTU on an annual basis and 1.0 NTU if the raw water was less than 10 NTU. Each filter was to meet 0.1 NTU 95% of the time except for the 15 minute period following placing the filter in operation. In addition, filters were expected to have maximum turbidity of 0.3 NTU and return to less than 0.1 NTU within 15 minutes of the filter being placed in service.

The primary purpose of the on-site evaluation was to confirm that the performance of the plant was consistent with Phase IV performance goals and that the system had the administrative support and operational capabilities to sustain the performance long-term. The on-site evaluation in Phase IV also allowed utilities that could not meet the desired performance goals to demonstrate to the third-party that they had achieved the highest level of performance given their unique raw water quality.

After the signing of the Stage 2 M–DBP Agreement in Principle in September 2000, the Partnership decided to eliminate the on-site third-party evaluation as a component of Phase IV. Instead, the requirement for Phase IV is for the water system to complete an application package that will be reviewed by trained utility volunteers. Included in the application package is an Optimization Assessment Spreadsheet in which the system enters water quality and treatment data to demonstrate that Phase IV performance levels have been achieved. The application also requires narratives related to administrative support and operational capabilities to sustain performance long-term.

Today's proposal is consistent with the performance goals of Phase IV.

Rather than require systems to complete an application package with historical data and narratives, the LT2ESWTR requires systems to demonstrate to the State that they meet the individual filter performance goals of Phase IV on an ongoing basis to receive the 1.0 log additional *Cryptosporidium* treatment credit. EPA is not requiring systems to demonstrate that they meet sedimentation performance goals of Phase IV. While EPA recognizes that settled water turbidity is an important operational performance measure for a plant, the Agency does not have data directly relating it to finished water quality and pathogen risk.

The November 2001 pre-proposal draft of the LT2ESWTR described a potential 1.0 log credit for systems that achieved individual filter effluent (IFE) turbidity below 0.15 NTU in 95 percent of samples (USEPA 2001g). The Science Advisory Board (SAB) subsequently reviewed this credit and supporting data on the relationship between filter effluent turbidity and *Cryptosporidium* removal efficiency (described in section IV.C.8). In written comments from a December 2001 meeting of the Drinking Water Committee, an SAB panel recommended only a 0.5 log credit for 95th percentile IFE turbidity below 0.15 NTU.

To address this recommendation from the SAB, EPA is proposing that systems meet the individual filter performance criteria of Phase IV of the Partnership in order to be eligible for a 1.0 log additional *Cryptosporidium* treatment credit. This proposed approach responds to the concerns raised by the SAB because the Phase IV criteria are more stringent than those in the 2001 pre-proposal draft of the LT2ESWTR. For example, today's proposal sets a maximum limit on individual filter effluent turbidity of 0.3 NTU, whereas no such upper limit was described in the 2001 pre-proposal draft.

In summary, EPA has concluded that it is appropriate to award additional *Cryptosporidium* treatment credit for systems meeting stringent individual filter performance standards. Modestly elevated turbidity from a single filter may not significantly impact combined filter effluent turbidity levels, which are regulated under IESWTR and LT1ESWTR, but may indicate a substantial reduction in the overall pathogen removal efficiency of the filtration process. Consequently, systems that continually achieve very low turbidity in each individual filter are likely to provide a significantly more effective microbial barrier. EPA expects that systems that select this toolbox option will have achieved a high level of treatment process optimization and process control, and will have both a history of consistent performance over a range of raw water quality conditions and the capability and resources to maintain this performance long-term.

c. *Request for comment.* The Agency invites comment on the following issues related to the proposed credit for individual filter performance.

- Are there different or additional performance measures that a utility should be required to meet for the 1 log additional credit?
- Are there existing peer review programs for which treatment credit should be awarded under the LT2ESWTR? If so, what role should primacy agencies play in establishing and managing any such peer review program?
- The individual filter effluent turbidity criterion of 0.1 NTU is proposed because it is consistent with Phase IV Partnership standards, as based on CCP goals. However, with allowable rounding, turbidity levels less than 0.15 NTU are in compliance with a standard of 0.1. Consequently, EPA requests comment on whether 0.15 NTU should be the standard for individual filter performance credit, as this would be consistent with the standard of 0.15 NTU that is proposed for combined filter performance credit in section IV.C.8.

17. Other Demonstration of Performance

a. *What is EPA proposing today?* The purpose of the ''demonstration of performance'' toolbox component is to allow a system to demonstrate that a plant, or a unit process within a plant, should receive a higher *Cryptosporidium* treatment credit than is presumptively awarded under the LT2ESWTR. For example, as described in section IV.A, plants using conventional treatment receive a presumptive 3 log credit towards the *Cryptosporidium* treatment requirements in Bins 2–4 of the LT2ESWTR. This credit is based on a determination by EPA that conventional treatment plants achieve an average *Cryptosporidium* removal of 3 log when in compliance with the IESWTR or LT1ESWTR. However, EPA recognizes that some conventional treatment plants may achieve average *Cryptosporidium* removal efficiencies greater than 3 log. Similarly, some systems may achieve *Cryptosporidium* reductions with certain toolbox components that are greater than the presumptive credits awarded under the LT2ESWTR, as described in this section (IV.C).

Where a system can demonstrate that a plant, or a unit process within a plant, achieves a *Cryptosporidium* reduction efficiency greater than the presumptive credit specified in the LT2ESWTR, it may be appropriate for the system to receive a higher *Cryptosporidium* treatment credit. Today's proposal does not include specific protocols for systems to make such a demonstration, due to the potentially complex and site specific nature of the testing that would be required. Rather, today's proposal allows a State to award a higher level of *Cryptosporidium* treatment credit to a system where the State determines, based on site-specific testing with a State-approved protocol, that a treatment plant or a unit process within a plant reliably achieves a higher level of *Cryptosporidium* removal on a continuing basis. Also, States may award a lower level of *Cryptosporidium* treatment credit to a system where a State determines, based on site specific information, that a plant or a unit process within a plant achieves a *Cryptosporidium* removal efficiency less than a presumptive credit specified in the LT2ESWTR.

Systems receiving additional *Cryptosporidium* treatment credit through a demonstration of performance may be required by the State to report operational data on a monthly basis to establish that conditions under which demonstration of performance credit was awarded are maintained during routine operation. The Toolbox Guidance Manual (USEPA 2003f) will describe potential approaches to demonstration of performance testing. This guidance is available in draft in the docket for today's proposal (*http://www.epa.gov/edocket/*).

Note that as described in section IV.C, today's proposal allows treatment plants to achieve additional *Cryptosporidium* treatment credit through meeting the design and/or operational criteria of microbial toolbox components, such as combined and individual filter performance, presedimentation, bank filtration, two-stage softening, secondary filtration, etc. Plants that receive additional *Cryptosporidium* treatment credit through a demonstration of performance are not also eligible for the presumptive credit associated with microbial toolbox components if the additional removal due to the toolbox component is captured in the demonstration of performance credit. For example, if a plant receives a demonstration of performance credit based on removal of *Cryptosporidium* or an indicator while operating under conditions of lower finished water turbidity, the plant may not also receive additional presumptive credit for lower

finished water turbidity toolbox components.

This demonstration of performance credit does not apply to the use of chlorine dioxide, ozone, or UV light, because today's proposal includes specific provisions allowing the State to modify the standards for awarding disinfection credit to these technologies. As described in section IV.C.14, States can approve site-specific CT values for inactivation of *Cryptosporidium* by chlorine dioxide and ozone; as described in section IV.C.15, States can approve an alternative approach for validating the performance of UV reactors.

b. *How was this proposal developed?* The Stage 2 M–DBP Agreement in Principle recommends demonstration of performance as a process for systems to receive *Cryptosporidium* treatment credit higher than the presumptive credit for many microbial toolbox components, as well as credit for technologies not listed in the toolbox. EPA is aware that there may be plants where particular unit processes, or combinations of unit processes, achieve greater *Cryptosporidium* removal than the presumptive credit awarded under the LT2ESWTR. In addition, the Agency would like to allow for the use of *Cryptosporidium* treatment processes not addressed in the LT2ESWTR, where such processes can demonstrate a reliable specific log removal. Due to these factors, EPA is proposing a demonstration of performance component in the microbial toolbox, consistent with the Advisory Committee recommendation.

The Agreement in Principle makes no recommendations for how a demonstration of performance should be conducted. It is generally not practical for systems to directly quantify high log removal of *Cryptosporidium* in treatment plants because of the relatively low occurrence of *Cryptosporidium* in many raw water sources and limitations with analytical methods. Consequently, if systems are to demonstrate the performance of full scale plants in removing *Cryptosporidium*, this typically will require the use of indicators, where the removal of the indicator has been correlated with the removal of *Cryptosporidium*. As described previously, a number of studies have shown that aerobic spores are an indicator of *Cryptosporidium* removal by sedimentation and filtration (Dugan *et al.* 2001, Emelko *et al.* 1999 and 2000, Yates *et al.* 1998, Mazounie *et al.* 2000).

The nature of demonstration of performance testing that will be appropriate at a given facility will depend on site specific factors, such as water quality, the particular process(es) being evaluated, resources and infrastructure, and the discretion of the State. Consequently, EPA is not proposing specific criteria for demonstration of performance testing. Instead, systems must develop a testing protocol that is approved by the State, including any requirements for ongoing reporting if demonstration of performance credit is approved. EPA has developed a draft document, Toolbox Guidance Manual (USEPA 2003f), that is available with today's proposal and provides guidance on demonstration of performance testing.

c. *Request for comment.* The Agency requests comment on today's proposal for systems to demonstrate higher *Cryptosporidium* removal levels. EPA specifically requests comment on the following issues:

- Approaches that should be considered or excluded for demonstration of performance testing;
- Whether EPA should propose minimum elements that demonstration of performance testing must include;
- Whether a factor of safety should be applied to the results of demonstration of performance testing to account for potential differences in removal of an indicator and removal of *Cryptosporidium*, or uncertainty in the application of pilot-scale results to full-scale plants;
- Whether or under what conditions a demonstration of performance credit should be allowed for a unit process within a plant—a potential concern is that certain unit processes, such as a sedimentation basin, can be operated in a manner that will increase removal in the unit process but decrease removal in subsequent treatment processes and, therefore, lead to no overall increase in removal through the plant. An approach to address this concern is to limit demonstration of performance credit to removal demonstrated across the entire treatment plant.

D. Disinfection Benchmarks for Giardia lamblia and Viruses

1. What Is EPA Proposing Today?

EPA proposes to establish the disinfection benchmark under the LT2ESWTR as a procedure to ensure that systems maintain protection against microbial pathogens as they implement the Stage 2 M–DBP rules (*i.e.*, Stage 2 DBPR and LT2ESWTR). The disinfection benchmark serves as a tool for systems and States to evaluate the impact on microbial risk of proposed changes in disinfection practice. EPA established the disinfection benchmark under the IESWTR and LT1ESWTR for the Stage 1 M–DBP rules, as recommended by the Stage 1 M–DBP Advisory Committee. Today's proposal extends disinfection benchmark requirements to apply to the Stage 2 M–DBP rules.

Under the proposed LT2ESWTR, the disinfection benchmark procedure involves a system charting levels of *Giardia lamblia* and virus inactivation at least once per week over a period of at least one year. This creates a profile of inactivation performance that the System must use to determine a baseline or benchmark of inactivation against which proposed changes in disinfection practice can be measured. Only certain systems are required to develop profiles and keep them on file for State review during sanitary surveys. When those systems that are required to develop a profile plan a significant change in disinfection practice (defined later in this section), they must submit the profile and an analysis of how the proposed change will affect the current disinfection benchmark to the State for review.

Systems that developed disinfection profiles under the IESWTR or LT1ESWTR and have not made significant changes in their disinfection practice or changed sources are not required to collect additional operational data to create disinfection profiles under the LT2ESWTR. Systems that produced a disinfection profile for *Giardia lamblia* but not viruses under the IESWTR or LT1ESWTR may be required to develop a profile for viruses under the LT2ESWTR. Where a previously developed *Giardia lamblia* profile is acceptable, systems may develop a virus profile using the same operational data (*i.e.*, CT values) on which the *Giardia lamblia* profile is based. Spreadsheets developed by EPA and States automatically calculate *Giardia lamblia* and virus profiles using the same operational data. EPA believes that virus profiling is necessary because many of the disinfection processes that systems will select to comply with the Stage 2 DBPR and LT2ESWTR (*e.g.*, chloramines, UV, MF/UF) are relatively less effective against viruses than *Giardia lamblia* in comparison to free chlorine.

The disinfection benchmark provisions contain three major components: (a) Applicability requirements and schedule, (b) characterization of disinfection practice, and (c) State review of proposed changes in disinfection practice. Each of these components is discussed in the following paragraphs.

a. *Applicability and schedule.* Proposed disinfection profiling and benchmarking requirements apply to surface water systems only. Systems serving only ground water are not subject to the requirements of the LT2ESWTR. The determination of whether a surface water system is required to develop a disinfection profile is based on whether DBP levels (TTHM or HAA5) exceed specified values, described later in this section, and whether a system is required to monitor for *Cryptosporidium*. These criteria trigger profiling because they identify systems that may be required to make treatment changes under the Stage 2 DBPR or LT2ESWTR. Note that it is not practical to wait until a system has completed *Cryptosporidium* monitoring to identify which systems should prepare a disinfection profile. A completed disinfection profile should be available at the point when a system is classified in a treatment bin and must begin developing plans to comply with any additional treatment requirements.

Unless the system developed a disinfection profile under the IESWTR or LT1ESWTR, all systems required to monitor for *Cryptosporidium* must develop *Giardia lamblia* and virus disinfection profiles under the LT2ESWTR. This includes all surface water systems except (1) systems that provide 5.5 log total treatment for *Cryptosporidium*, equivalent to meeting the treatment requirements of Bin 4 and (2) small systems (<10,000 people served) that do not exceed the *E. coli* trigger (see section IV.A for details). Systems not required to monitor for *Cryptosporidium* as a result of providing 5.5 log of treatment are not required to prepare disinfection profiles. However, small systems that do not exceed the *E. coli* trigger are required to prepare *Giardia lamblia* and virus disinfection profiles if one of the following criteria apply, based on DBP levels in their distribution systems:

(1)* TTHM levels in the distribution system, based on samples collected for compliance with the Stage 1 DBPR, are at least 80% of the MCL (0.064 mg/L) at any Stage 1 DBPR sampling point based on a locational running annual average (LRAA).

(2)* HAA5 levels in the distribution system, based on the samples collected for compliance with the Stage 1 DBPR, are at least 80% of the MCL (0.048 mg/L) at any Stage 1 DBPR sampling point based on an LRAA.

*These criteria only apply to systems that are required to comply with the DBP rules, *i.e.*, community and non-transient non-community systems.

Table IV–22 presents a summary schedule of the required deadlines for disinfection profiling activities, categorized by system size and whether a small system is required to monitor for *Cryptosporidium*. The deadlines are based on the expectation that a system should have a disinfection profile at the time the system is classified in a *Cryptosporidium* treatment bin under LT2ESWTR and/or has determined the need to make treatment changes for the Stage 2 DBPR. Systems have three years from this date, with a possible two year extension for capital improvements if granted by the State, within which to complete their evaluation, design, and implementation of treatment changes to meet the requirements of the LT2ESWTR and the Stage 2 DBPR.

TABLE IV–22.—SCHEDULE OF IMPLEMENTATION DEADLINES RELATED TO DISINFECTION PROFILING [1]

Activity	Systems serving ≥10,000 people [2]	Systems serving <10,000 people	
		Required to monitor for *Cryptosporidium*	Not required to monitor for *Cryptosporidium* [2 3 6]
Complete 1 year of *E. coli* monitoring	NA	42	42
Determine whether required to profile based on DBP levels and notify State [6]	NA	NA	42
Begin disinfection profiling [4]	24	54	42
Complete *Cryptosporidium* monitoring	30	60	NA
Complete disinfection profiling based on at least one year's data [5]	36	66	54

[1] Numbers in table indicate months following promulgation of the LT2ESWTR.
[2] Systems providing a total of 5.5 log *Cryptosporidium* treatment (equivalent to meeting Bin 4 treatment requirements) are not required to develop disinfection profiles.
[3] Systems serving fewer than 10,000 people are not required to monitor for *Cryptosporidium* if mean *E. coli* levels are less than 10/100 mL for systems using lake/reservoir sources or less than 50/100 mL for systems using flowing stream sources.
[4] Unless system has existing disinfection profiling data that are acceptable.
[5] This deadline coincides with the start of the 3 year period at the end of which compliance with the LT2ESWTR and Stage 2 DBPR is required.
[6] Not required to conduct profiling unless TTHM or HAA5 exceeds trigger values of 80% of MCL at any sampling point based on LRAA.

As described in the next section, systems can meet profiling requirements under the proposed LT2ESWTR using previously collected data (*i.e.*, grandfathered data). Use of grandfathered data is allowed if the system has not made a significant change in disinfection practice or changed sources since the data were collected. This will permit most systems that prepared a disinfection profile under the IESWTR or the LT1ESWTR to avoid collecting any new operational data to develop profiles under the LT2ESWTR.

The locational running annual average (LRAA) of TTHM and HAA5 levels used by small systems that do not monitor for *Cryptosporidium* to determine whether profiling is required must be based on one year of DBP data collected during the period following promulgation of the LT2ESWTR, or as determined by the State. By the date indicated in Table IV–22, these systems must report to the State on their DBP LRAAs and whether the disinfection profiling requirements apply. If either DBP LRAA meets the criteria specified previously, the system must begin disinfection profiling by the date proposed in Table IV–22.

b. *Developing the disinfection profile and benchmark.* Under the LT2ESWTR, a disinfection profile consists of a compilation of *Giardia lamblia* and virus log inactivation levels computed at least weekly over a period of at least one year, as based on operational and water quality data (disinfectant residual concentration(s), contact time(s), temperature(s), and, where necessary, pH). The system may create the profile by conducting new weekly (or more frequent) monitoring and/or by using

grandfathered data. A system that created a *Giardia lamblia* disinfection profile under the IESWTR or LT1ESWTR may use the operational data collected for the *Giardia lamblia* profile to create a virus disinfection profile.

Grandfathered data are those operational data that a system has previously collected at a treatment plant during the course of normal operation. Those systems that have all the necessary information to determine profiles using existing operational data collected prior to the date when the system is required to begin profiling may use these data in developing profiles. However, grandfathered data must be substantially equivalent to operational data that would be collected under this rule. These data must be representative of inactivation through the entire treatment plant and not just of certain treatment segments.

To develop disinfection profiles under this rule, systems are required to exercise one of the following three options:

Option 1—Systems conduct monitoring at least once per week following the process described later in this section.

Option 2—Systems that conduct monitoring under this rule, as described under Option 1, can also use one or two years of acceptable grandfathered data, in addition to one year of new operational data, in developing the disinfection profile.

Option 3—Systems that have at least one year of acceptable existing operational data are not required to conduct new monitoring to develop the disinfection profile under this rule. Instead, they can use a disinfection profile based on one to three years of grandfathered data.

Process to be followed by PWS for developing the disinfection profile:

—Measure disinfectant residual concentration (C, in mg/L) before or at the first customer and just prior to each additional point of disinfectant addition, whether with the same or a different disinfectant.
—Determine contact time (T, in minutes) for each residual disinfectant monitoring point during peak flow conditions. T could be based on either a tracer study or assumptions based on contactor basin geometry and baffling. However, systems must use the same method for both grandfathered data and new data.
—Measure water temperature (°C) (for disinfectants other than UV).
—Measure pH (for chlorine only).

To determine the weekly log inactivation, the system must convert operational data from one day each week to the corresponding log inactivation values for *Giardia lamblia* and viruses. The procedure for *Giardia lamblia* is as follows:

—Determine CT_{calc} for each disinfection segment.
—Determine $CT_{99.9}$ (*i.e.*, 3 log inactivation) from tables in the SWTR (40 CFR 141.74) using temperature (and pH for chlorine) for each disinfection segment. States can allow an alternate calculation procedure (*e.g.*, use of a spreadsheet).
—For each segment, log inactivation = $(CT_{calc}/CT_{99.9}) \times 3.0$.
—Sum the log inactivation values for each segment to get the log inactivation for the day (or week).

For calculating the virus log inactivation, systems should use the procedures approved by States under the IESWTR or LT1ESWTR. Log inactivation benchmark is calculated as follows:

—Determine the calendar month with the lowest log inactivation.
—The lowest month becomes the critical period for that year.
—If acceptable data from multiple years are available, the average of critical periods for each year becomes the benchmark.
—If only one year of data is available, the critical period for that year is the benchmark.

c. *State review.* If a system that is required to produce a disinfection profile proposes to make a significant change in disinfection practice, it must calculate *Giardia lamblia* and virus inactivation benchmarks and must notify the State before implementing such a change. Significant changes in disinfection practice are defined as (1) moving the point of disinfection (this is not intended to include routine seasonal changes already approved by the State), (2) changing the type of disinfectant, (3) changing the disinfection process, or (4) making other modifications designated as significant by the State. When notifying the State, the system must provide a description of the proposed change, the disinfection profiles and inactivation benchmarks for *Giardia lamblia* and viruses, and an analysis of how the proposed change will affect the current inactivation benchmarks. In addition, the system should have disinfection profiles and, if applicable, inactivation benchmarking documentation, available for the State to review as part of its periodic sanitary survey.

EPA developed for the IESWTR, with stakeholder input, the Disinfection Profiling and Benchmarking Guidance Manual (USEPA 1999d). This manual provides guidance to systems and States on the development of disinfection profiles, identification and evaluation of significant changes in disinfection practices, and considerations for setting an alternative benchmark. If necessary, EPA will produce an addendum to reflect changes in the profiling and benchmarking requirements necessary to comply with LT2ESWTR.

2. How Was This Proposal Developed?

A fundamental premise in the development of the M–DBP rules is the concept of balancing risks between DBPs and microbial pathogens. Disinfection profiling and benchmarking were established under the IESWTR and LT1ESWTR, based on a recommendation by the Stage 1 M–DBP Federal Advisory Committee, to ensure that systems maintained adequate control of pathogen risk as they reduced risk from DBPs. Today's proposal would extend disinfection benchmarking requirements to the LT2ESWTR.

EPA believes this extension is necessary because some systems will make significant changes in their current disinfection practice to meet more stringent limits on TTHM and HAA5 levels under the Stage 2 DBPR and additional *Cryptosporidium* treatment requirements under the LT2ESWTR. In order to ensure that these systems continue to provide adequate protection against the full spectrum of microbial pathogens, it is appropriate for systems and States to evaluate the effects of such treatment changes on microbial drinking water quality. The disinfection benchmark serves as a tool for making such evaluations.

EPA projects that to comply with the Stage 2 DBPR, systems will make changes to their disinfection practice, including switching from free chlorine to chloramines and, to a lesser extent, installing technologies like ozone, membranes, and UV. Similarly, to provide additional treatment for *Cryptosporidium*, some systems will install technologies like UV, ozone, and microfiltration. While these processes are all effective disinfectants, chloramines are a weaker disinfectant than free chlorine for *Giardia lamblia*. Ozone, UV, and membranes can provide highly effective treatment for *Giardia lamblia*, but they, as well as chloramines, are less efficient for treating viruses than free chlorine, relative to their efficacy for *Giardia lamblia*. Because of this, a system switching from free chlorine to one of these alternative disinfection

technologies could experience a reduction in the level of virus and/or *Giardia lamblia* (for chloramines) treatment it is achieving. Consequently, EPA believes that systems making significant changes in their disinfection practice under the Stage 2 M–DBP rules should assess the impact of these changes with disinfection benchmarks for *Giardia lamblia* and viruses.

Changes in the proposed benchmarking requirements under the LT2ESWTR in comparison to IESWTR requirements include decreasing the frequency of calculating CT values for the disinfection profile from daily to weekly and requiring all systems to prepare a profile for viruses as well as *Giardia lamblia*. The proposal of a weekly frequency for CT calculations was made to accommodate existing profiles from small systems, which are required to make weekly CT calculations for profiling under the LT1ESWTR. As described earlier, EPA would like for systems that have prepared a disinfection profile under the IESWTR or LT1ESWTR and have not subsequently made significant changes in disinfection practice to be able to grandfather this profile for the LT2ESWTR. Allowing weekly calculation of CT values under the LT2ESWTR will make this possible.

The IESWTR and LT1ESWTR required virus inactivation profiling only for systems using ozone or chloramine as their primary disinfectant. However, as noted earlier, EPA has projected that under the Stage 2 DBPR and LT2ESWTR, systems will switch from free chlorine to disinfection processes like chloramines, UV, ozone, and microfiltration. The efficiency of these processes for virus treatment relative to protozoa treatment is lower in comparison to free chlorine. As a result, a disinfection benchmark for *Giardia lamblia* would not necessarily provide an indication of the level or adequacy of treatment for viruses. Consequently, EPA believes it is appropriate for systems to develop profiles for both *Giardia lamblia* and viruses. Moreover, developing a profile for viruses involves a minimal increase in effort and no additional data collection for those systems that have disinfection profiles for *Giardia lamblia*. Systems will use the same calculated CT values for viruses as would be used for the *Giardia lamblia* profile.

The strategy of disinfection profiling and benchmarking stemmed from data provided to the Stage1 M–DBP Advisory Committee, in which the baseline of microbial inactivation (expressed as logs of *Giardia lamblia* inactivation) demonstrated high variability. Inactivation varied by several logs (*i.e.*, orders of magnitude) on a day-to-day basis at particular treatment plants and by as much as tens of logs over a year due to changes in water temperature, flow rate, seasonal changes, pH, and disinfectant demand. There were also differences between years at individual plants. To address these variations, M–DBP stakeholders developed the procedure of profiling a plant's inactivation levels over a period of at least one year, and then establishing a benchmark of minimum inactivation as a way to characterize disinfection practice.

Benchmarking of inactivation levels, an assessment of the impact of proposed changes on the level of microbial inactivation of *Giardia lamblia* and viruses, and State review prior to approval of substantial changes in treatment are important steps in avoiding conditions that present an increase in microbial risk. In its assessment of the microbial risk associated with the proposed changes, States could consider site-specific knowledge of the watershed and hydrologic factors as well as variability, flexibility and reliability of treatment to ensure that treatment for both protozoan and viral pathogens is appropriate.

EPA emphasizes that benchmarking is not intended to function as a regulatory standard. Rather, the objective of the disinfection benchmark is to facilitate interactions between the States and systems for the purpose of assessing the impact on microbial risk of proposed significant changes to current disinfection practices. Final decisions regarding levels of disinfection for *Giardia lamblia* and viruses beyond those required by the SWTR that are necessary to protect public health will continue to be left to the States. For this reason EPA has not mandated specific evaluation protocols or decision matrices for analyzing changes in disinfection practice. EPA, however, will provide support to the States in making these analyses through the issuance of guidance.

3. Request for Comments

EPA requests comment on the proposed provisions of the inactivation profiling and benchmarking requirement.

E. Additional Treatment Technique Requirements for Systems With Uncovered Finished Water Storage Facilities

1. What Is EPA Proposing Today?

EPA is proposing requirements for systems with uncovered finished water storage facilities. The proposed rule requires that systems with uncovered finished water storage facilities must (1) cover the uncovered finished water storage facility, or (2) treat storage facility discharge to the distribution system to achieve a 4 log virus inactivation, unless (3) the system implements a State-approved risk mitigation plan that addresses physical access and site security, surface water runoff, animal and bird waste, and ongoing water quality assessment, and includes a schedule for plan implementation. Where applicable, the plans should account for cultural uses by Indian Tribes.

Systems must notify the State if they use uncovered finished water storage facilities no later than 2 years following LT2ESWTR promulgation. Systems must cover or treat uncovered finished facilities or have a State-approved risk mitigation plan within 3 years following LT2ESWTR promulgation, with the possibility of a two year extension granted by States for systems making capital improvements. Systems seeking approval for a risk mitigation plan must submit the plan to the State within 2 years following LT2ESWTR promulgation.

These provisions apply to uncovered tanks, reservoirs, or other facilities where water is stored after it has undergone treatment to satisfy microbial treatment technique requirements for *Giardia lamblia*, *Cryptosporidium*, and viruses. In most cases, this refers to storage of water following all filtration steps, where required, and primary disinfection.

2. How Was This Proposal Developed?

Today's proposal is intended to mitigate the water quality degradation and increased health risks that can result from uncovered finished water storage facilities. In addition, these proposed requirements for uncovered finished water storage facilities are consistent with recommendations of the Stage 2 M–DBP Advisory Committee in the Agreement in Principle (USEPA 2000a).

The use of uncovered finished water storage facilities has been questioned since 1930 due to their susceptibility to contamination and subsequent threats to public health (LeChevallier *et al.* 1997). Many potential sources of contamination can lead to the degradation of water quality in uncovered finished water storage facilities. These include surface water runoff, algal growth, insects and fish, bird and animal waste, airborne deposition, and human activity.

Algal blooms are the most common problem in open reservoirs and can become a public health risk, as they increase the presence of bacteria in the water. Algae growth also leads to the formation of disinfection byproducts and causes taste and odor problems. Some algae produce toxins that can induce headache, fever, diarrhea, abdominal pain, nausea, and vomiting. Bird and animal wastes are also common and significant sources of contamination. These wastes may carry microbial contaminants such as coliform bacteria, viruses, and human pathogens, including Vibrio cholera, Salmonella, Mycobacteria, Typhoid, *Giardia lamblia*, and *Cryptosporidium* (USEPA 1999e). Microbial pathogens are found in surface water runoff, along with agricultural chemicals, automotive wastes, turbidity, metals, and organic matter (USEPA 1999e, LeChevallier *et al.* 1997).

In an effort to minimize contamination, systems have implemented various controls such as reservoir covers and liners, regular draining and washing, security and monitoring, bird and insect control programs, and drainage design to prevent surface runoff from entering the facility (USEPA 1999e).

A number of studies have evaluated the degradation of water quality in uncovered finished water storage facilities. LeChevallier *et al.* (1997) compared influent and effluent samples from six uncovered finished water storage reservoirs in New Jersey for a one year period. There were significant increases in the turbidity, particle count, total coliform, fecal coliform, and heterotrophic plate count bacteria in the effluent relative to the influent. Of particular concern were fecal coliforms, which were detected in 18 percent of effluent samples (no influent samples were positive for coliforms). Fecal coliforms are used as an indicator of the potential for contamination by pathogens. Giardia and/or *Cryptosporidium* were detected in 15% of inlet samples and 25% of effluent samples, demonstrating a significant increase in the effluent. There was a significant decrease in the chlorine residual concentration in some effluent samples.

Increases in algal cells, heterotrophic plate count (HPC) bacteria, turbidity, color, particle counts, and biomass, and decreases in residual chlorine levels, have been reported in other studies of uncovered finished water reservoirs as well (Pluntze 1974, AWWA Committee 1983, Silverman *et al.* 1983). Researchers have shown that small mammals, birds, fish, and algal growth contribute to the microbial degradation of an open finished water reservoir (Graczyk *et al.* 1996, Geldreich 1990, Fayer and Ungar 1986, Current 1986).

As described in section II, the IESWTR and LT1ESWTR require water systems to cover all new reservoirs, holding tanks, or other storage facilities for finished water. However, these rules do not require systems to cover existing finished water storage facilities. EPA stated in the preamble to the final IESWTR (63 FR 69494, December 16, 1998) (USEPA 1998a) that with respect to requirements for existing uncovered finished water storage facilities, the Agency needed more time to collect and analyze additional information to evaluate regulatory impact. The IESWTR preamble affirmed that EPA would consider whether to require the covering of existing storage facilities during the development of subsequent microbial regulations when additional data to estimate national costs were available.

Since promulgation of the IESWTR, EPA has collected sufficient data to estimate national cost implications of regulatory control strategies for uncovered finished water storage facilities. Based on information provided by States, EPA estimates that there are approximately 138 uncovered finished water storage facilities in the United States and territories, not including reservoirs that systems currently plan to cover or take off-line. Costs for covering these storage facilities or treating the effluent, consistent with today's proposed requirements, are presented in section VI of this preamble and in the Economic Analysis for the LT2ESWTR (USEPA 2003a). Briefly, total capital costs were estimated as $64.4 million, resulting in annualized present value costs of $5.4 million at a three percent discount rate and $6.4 million at a seven percent discount rate.

Based on the findings of studies cited in this section, EPA continues to be concerned about contamination occurring in uncovered finished water storage facilities. Therefore, as recommended by the Advisory Committee, EPA is proposing control measures for all systems with uncovered finished water storage facilities. This proposal is intended to represent a balanced approach, recognizing both the potentially significant but uncertain risks associated with uncovered finished water storage facilities and the substantial costs of either covering them or building alternative storage. Today's proposal allows systems to treat the storage facility effluent instead of providing a cover. Alternatively, States may determine that existing risk mitigation is adequate, provided a system implements a risk mitigation plan as described in this section.

3. Request for Comments

EPA requests comment on the proposed requirements pertaining to uncovered finished water storage facilities. Specifically, the Agency would like comment on the following issues, and requests that comments include available supporting data or other technical information:

- Is it appropriate to allow systems with uncovered finished water storage facilities to implement a risk management plan or treat the effluent to inactivate viruses instead of covering the facility?
- If systems treat the effluent of an uncovered finished water storage facility instead of covering it, should systems be required to inactivate *Cryptosporidium* and *Giardia lamblia*, since these protozoa have been found to increase in uncovered storage facilities?
- Additional information on contamination or health risks that may be associated with uncovered finished water storage facilities.
- Additional data on how climatological conditions affect water quality, including daily fluctuations in the stability of the water related to corrosion control.
- The definition of an uncovered finished water storage facility in 40 CFR 141.2 is a tank, reservoir, or other facility used to store water that will undergo no further treatment except residual disinfection and is open to the atmosphere. There is a concern that this definition may not include certain systems using what would generally be considered an uncovered finished water storage facility. An example is a system that applies a corrosion inhibitor compound to the effluent of an uncovered storage facility where water is stored after filtration and primary disinfection. In this case, the system may claim that the corrosion inhibitor constitutes additional treatment and, consequently, the reservoir does not meet EPA's definition of an uncovered finished water storage facility. EPA requests comment on whether the definition of an uncovered finished water storage facility should be revised to specifically include systems that apply a treatment such as corrosion control to water stored in an uncovered reservoir after the water has undergone filtration, where required, and primary disinfection.

F. Compliance Schedules

Today's proposal includes deadlines for public water systems to comply with

the proposed monitoring, reporting, and treatment requirements. These deadlines stem from the microbial framework approach of the proposed LT2ESWTR, which involves a system-specific risk characterization through monitoring to determine the need for additional treatment.

1. What Is EPA Proposing Today?

a. Source water monitoring.

i. Filtered systems. Under today's proposal, filtered systems conduct source water *Cryptosporidium* monitoring for the purpose of being classified in one of four risk bins that determine the extent of any additional treatment requirements. Small filtered systems first monitor for *E. coli* as a screening analysis and are only required to monitor for *Cryptosporidium* if the mean *E. coli* level exceeds specified trigger values. Note that systems that currently provide or will provide a total of at least 5.5 log of treatment for *Cryptosporidium* are exempt from monitoring requirements.

Large surface water systems (serving at least 10,000 people) that filter must sample at least monthly for *Cryptosporidium*, *E. coli*, and turbidity in their source water for 24 months, beginning 6 months after promulgation of the LT2ESWTR. Large systems must submit a sampling schedule to their primacy agency (in this case, EPA) no later than 3 months after promulgation of the LT2ESWTR.

Small surface water systems (fewer than 10,000 people served) that filter must conduct biweekly *E. coli* sampling in their source water for 1 year, beginning 30 months after LT2ESWTR promulgation. States may designate an alternate indicator monitoring strategy based on EPA guidance, but compliance schedules will not change. Small systems that exceed the indicator trigger value (*i.e.*, mean *E. coli* > 10/100 mL for lake/reservoir sources or > 50/100 mL for flowing stream sources) must conduct source water *Cryptosporidium* sampling twice-per-month for 1 year, beginning 48 months after LT2ESWTR promulgation (*i.e.*, beginning 6 months following the completion of *E. coli* sampling). Small systems must submit an *E. coli* sampling schedule to their primacy agency no later than 27 months after LT2ESWTR promulgation. If *Cryptosporidium* monitoring is required, small systems must submit a *Cryptosporidium* sampling schedule no later than 45 months after LT2ESWTR promulgation.

Large systems must carry out a second round of source water monitoring beginning 108 months after LT2ESWTR promulgation, which is 6 years after initial bin classification. Similarly, small systems must conduct a second round of indicator monitoring (*E. coli* or other as designated by the State) beginning 138 months after LT2ESWTR promulgation, which is 6 years after their initial bin classification. Small systems that exceed the indicator trigger value in the second round of indicator monitoring must conduct a second round of *Cryptosporidium* monitoring, beginning 156 months after LT2ESWTR promulgation.

Compliance dates for filtered systems are summarized in Table IV–23.

TABLE IV–23.—SUMMARY OF COMPLIANCE DATES FOR FILTERED SYSTEMS

System type	Requirement	Compliance date
Large Systems (serve ≥10,000 people).	Submit sampling schedule [1,2]	No later than 3 months after promulgation.
	Source water *Cryptosporidium*, *E. coli* and turbidity monitoring.	Begin monthly monitoring 6 months after promulgation for 24 months.
	Comply with additional *Cryptosporidium* treatment requirements.	No later than 72 months after promulgation.[3]
	Second round of source water *Cryptosporidium*, *E. coli*, and turbidity monitoring [2].	Begin monthly monitoring 108 months after promulgation for 24 months.
Small Systems (serve <10,000 people).	Submit *E. coli* sampling schedule[2]	No later than 27 months after promulgation.
	Source water *E. coli* monitoring	Begin biweekly monitoring 30 months after promulgation for 1 year.
	Second round of source water *E. coli* monitoring [2]	Begin biweekly monitoring 138 months after promulgation for 1 year.
	Additional requirements if indicator (*e.g.*, *E. coli*) trigger level is exceeded[4]	
	Submit *Cryptosporidium* sampling schedule [1,2]	No later than 45 months after promulgation.
	Source water *Cryptosporidium* monitoring	Begin twice-per-month monitoring no later than 48 months after promulgation for 1 year.
	Comply with additional *Cryptosporidium* treatment requirements.	No later than 102 months after promulgation.[3, 5]
	Second round of source water *Cryptosporidium* monitoring.	Begin twice-per-month monitoring no later than 156 months after promulgation for 1 year.

[1] Systems may be eligible to use previously collected (grandfathered) data to meet LT2ESWTR requirements if specified quality control criteria are met (described in section IV.A.1.d).

[2] Systems are not required to monitor if they will provide at least 5.5 log *Cryptosporidium* treatment and notify EPA or the State.

[3] States may grant up to an additional two years for systems making capital improvements.

[4] If the *E. coli* annual mean concentration exceeds 10/100 mL for systems using lakes/reservoir sources or exceeds 50/100 mL for systems using flowing stream sources, *Cryptosporidium* monitoring is required.

[5] Systems that do not exceed the *E. coli* trigger level are classified in Bin 1 and are not required to provide *Cryptosporidium* treatment beyond LT1ESWTR levels.

ii. *Unfiltered systems.* Surface water systems that do not filter and meet the criteria for avoidance of filtration (40 CFR 141.71) (*i.e.*, unfiltered systems) are required to conduct source water *Cryptosporidium* monitoring to determine if their mean source water *Cryptosporidium* level exceeds 0.01 oocysts/L. There is no *E. coli* screening analysis available to small unfiltered systems. However, both large and small unfiltered systems conduct

Cryptosporidium monitoring on the same schedule as filtered systems of the same size. Note that unfiltered systems that currently provide or will provide a total of at least 3 log *Cryptosporidium* inactivation are exempt from monitoring requirements.

Large unfiltered systems (serving at least 10,000 people) must conduct at least monthly *Cryptosporidium* sampling for 24 months, beginning 6 months after LT2ESWTR promulgation. Small unfiltered systems (serving fewer than 10,000 people) must conduct at least twice-per-month *Cryptosporidium* sampling for 12 months, beginning 48 months after LT2ESWTR promulgation. Large systems must submit a *Cryptosporidium* sampling schedule to EPA no later than 3 months after LT2ESWTR promulgation, and small systems must submit a sampling schedule to their State no later than 45 months after LT2ESWTR promulgation.

Unfiltered systems are required to conduct a second round of *Cryptosporidium* monitoring on the same schedule as filtered systems of the same size. Large systems must carry out a second round of *Cryptosporidium* monitoring, beginning 108 months after LT2ESWTR promulgation. Small systems must perform a second round of *Cryptosporidium* monitoring, beginning 156 months after LT2ESWTR promulgation.

Compliance dates for unfiltered systems are summarized in Table IV–24.

TABLE IV–24.—SUMMARY OF COMPLIANCE DATES FOR UNFILTERED SYSTEMS

System type	Requirement	Compliance date
Large Systems (serve ≥10,000 people).	Submit sampling schedule [1]	No later than 3 months after promulgation.
	Source water *Cryptosporidium* monitoring	Begin monthly monitoring [6 months after promulgation for 24 months.
	Comply with *Cryptosporidium* inactivation requirements.	No later than 72 months after promulgation.[2]
	Second round of source water *Cryptosporidium* monitoring.	Begin monthly monitoring 108 months after promulgation for 24 months.
Small Systems (serve < 10,000 people).	Submit sampling schedule [1]	No later than 45 months after promulgation.
	Source water *Cryptosporidium* monitoring	Begin twice-per-month monitoring no later than 48 months after promulgation for 1 year.
	Comply with *Cryptosporidium* inactivation requirements.	No later than 102 months after promulgation.[2]
	Second round of source water *Cryptosporidium* monitoring.	Begin twice-per-month monitoring no later than 156 months after promulgation for 1 year.

[1] Systems may be eligible to use previously collected (grandfathered) data to meet LT2ESWTR requirements if specified quality control criteria are met (described in section IV.A.1.d).

[2] States may grant up to an additional two years for systems making capital improvements.

b. *Treatment requirements.* Filtered systems must determine their bin classification and unfiltered systems must determine their mean source water *Cryptosporidium* level within 6 months of the scheduled month for collection of their final *Cryptosporidium* sample in the first round of monitoring. This 6 month period provides time for systems to receive all sample analysis results from the laboratory, analyze the data, and work with their primacy agency.

Filtered systems have 3 years following initial bin classification to meet any additional *Cryptosporidium* treatment requirements. This equates to compliance dates of 72 months after LT2ESWTR promulgation for large systems and 102 months after LT2ESWTR promulgation for small systems (see Table IV–23). Unfiltered systems must comply with *Cryptosporidium* treatment requirements on the same schedule as filtered systems of the same size (see Table IV–24). The State may grant systems an additional two years to comply when capital investments are necessary, as specified in the Safe Drinking Water Act (section 1412(b)(10)).

Systems with uncovered finished water storage facilities are required to comply with the provisions described in section IV.E by 36 months following LT2ESWTR promulgation, with the possibility of a 2 year extension granted by the State for systems making capital improvements. Systems seeking approval for a risk mitigation plan must submit the plan to the State within 24 months following LT2ESWTR promulgation.

Systems must comply with additional *Cryptosporidium* treatment requirements by implementing one or more treatment processes or control strategies from the microbial toolbox. Most of the toolbox components require submission of documentation to the State demonstrating compliance with design and/or implementation criteria required to receive credit. Compliance dates for reporting requirements associated with microbial toolbox components are presented in detail in section IV.J, Reporting and Recordkeeping Requirements.

c. *Disinfection benchmarks for Giardia lamblia and viruses.* Today's proposed LT2ESWTR includes disinfection profiling and benchmarking requirements, which consist of three major components: applicability determination, characterization of disinfection practice, and State review of proposed changes in disinfection practice. Each of these components is discussed in detail in section IV.D. Compliance deadlines associated with each of these components, including associated reporting requirements, are stated in section IV.J, Reporting and Recordkeeping Requirements.

2. How Was This Proposal Developed?

The compliance dates in today's proposal reflects the risk-targeted approach of the proposed LT2ESWTR, wherein additional treatment requirements are based on a system specific risk characterization as determined through source water monitoring. Additionally, they are designed to allow for systems to simultaneously comply with the LT2ESWTR and Stage 2 DBPR in order to balance risks in the control of microbial pathogens and DBPs. These dates are consistent with recommendations from the Stage 2 M–DBP Federal Advisory Committee.

Under the LT2ESWTR, large systems will sample for *Cryptosporidium* for a period of two years in order to

characterize source water pathogen levels and capture a degree of annual variability. To expedite the date by which systems will provide additional treatment where high risk source waters are identified, large system *Cryptosporidium* monitoring will begin six months after promulgation of the LT2ESWTR. Upon completion of *Cryptosporidium* monitoring, systems will have six months to work with their primacy agency to determine their bin classification. Beginning at this point, which is three years following LT2ESWTR promulgation, large systems will have three years to implement the treatment processes or control strategies necessary to comply with any additional treatment requirements stemming from bin classification.

Other large system compliance dates in areas like approval of grandfathered monitoring data, disinfection profiling and benchmarking, and reporting deadlines associated with microbial toolbox components all stem from the *Cryptosporidium* monitoring and treatment compliance schedule.

With respect to small systems under the LT2ESWTR, EPA is proposing that small systems first monitor for *E. coli* as a screening analysis in order to reduce the number of small systems that incur the cost of *Cryptosporidium* monitoring. However, due to limitations in available data, the Agency has determined that it is necessary to use data generated by large systems under the LT2ESWTR to confirm or refine the *E. coli* indicator criteria that will trigger small system *Cryptosporidium* monitoring. Consequently, small system indicator monitoring will begin at the conclusion of large system monitoring. This approach was recommended by the Advisory Committee.

Accordingly, small systems will monitor for *E. coli* for one year, beginning 30 months after LT2ESWTR promulgation. Following this, small systems will have six months to determine if they are required to monitor for *Cryptosporidium* and, if so, contract with an approved analytical laboratory. *Cryptosporidium* monitoring by small systems will be conducted for one year, which, when added to the one year of *E. coli* monitoring, equals two years of source water monitoring. This is equivalent to the time period large systems spend in source water monitoring.

The time periods associated with bin assignment and compliance with additional treatment requirements for small systems are the same as those proposed for large systems. Specifically, small systems will have six months to work with their States to determine their bin classification following the conclusion of *Cryptosporidium* sampling. From this point, which is 5.5 years after LT2ESWTR promulgation, small systems have three years to meet any additional treatment requirements resulting from bin classification. States can grant additional time to small systems for compliance with treatment technique requirements through granting exemptions (see SDWA section 1416).

3. Request for Comments

EPA requests comments on the treatment technique compliance schedules for large and small systems in today's proposal, including the following issues:

Time Window Between Large and Small System Monitoring

Under the current proposal, small filtered system *E. coli* monitoring begins in the month following the end of large system *Cryptosporidium*, *E. coli*, and turbidity monitoring. EPA plans to evaluate large system monitoring results on an ongoing basis as the data are reported to determine if any refinements to the *E. coli* levels that trigger small system *Cryptosporidium* monitoring are necessary. If such refinements were deemed appropriate, EPA would issue guidance to States, which can establish alternative trigger values for small system monitoring under the LT2ESWTR.

This implementation schedule does not leave any time between the end of large system monitoring and the initiation of small system monitoring. Consequently, if it is necessary to provide guidance on alternative trigger values prior to when small system monitoring begins, such guidance would be based on less than the full set of large system results (*e.g.*, first 18 months of large system data). EPA requests comment on whether an additional time window between the end of large system monitoring and the beginning of small system monitoring is appropriate and, if so, how long such a window should be.

Implementation Schedule for Consecutive Systems

The Stage 2 M–DBP Agreement in Principle (65 FR 83015, December 29, 2000) (USEPA 2000a) continues the principle of simultaneous compliance to address microbial pathogens and disinfection byproducts. Systems are generally expected to address LT2ESTWR requirements concurrently with those of the Stage 2 DBPR (as noted earlier, the Stage 2 DBPR is scheduled to be proposed later this year and to be promulgated at the same time as the LT2ESWTR).

As with the LT2ESWTR, small water systems (< 10,000 served) generally begin monitoring and must be in compliance with the Stage 2 DBPR at a date later than that for large systems. However, the Advisory Committee recommended that small systems that buy/receive from or sell/deliver finished water to a large system (that is, they are part of the same ''combined distribution system'') comply with Stage 2 DBPR requirements on the same schedule as the largest system in the combined distribution system. This approach is intended to ensure that systems consider impacts throughout the combined distribution system when making compliance decisions (*e.g,* selecting new technologies or making operational modifications) and to facilitate all systems meeting the compliance deadlines for the rule.

The issue of combined distribution systems associated with systems buying and selling water is expected to be of less significance for the LT2ESWTR. The requirements of the LT2ESWTR apply to systems treating raw surface water and generally will not involve compliance steps when systems purchase treated water. Consequently, the compliance schedule for today's proposal does not address combined distribution systems. However, this proposed approach raises the possibility that a small system treating surface water and selling it to a large system could be required to take compliance steps at an earlier date under the Stage 2 DBPR than under the LT2ESWTR. While a small system in this situation could choose to comply with the LT2ESWTR on an earlier schedule, the two rules would not require simultaneous compliance. EPA requests comment on how this scenario should be addressed in the LT2ESWTR.

G. Public Notice Requirements

1. What Is EPA Proposing Today?

EPA is proposing that under the LT2ESWTR, a Tier 2 public notice will be required for violations of additional treatment requirements and a Tier 3 public notice will be required for violations of monitoring and testing requirements. Where systems violate LT2ESWTR treatment requirements, today's proposal requires the use of the existing health effects language for microbiological contaminant treatment technique violations, as stated in 40 CFR 141 Subpart Q, Appendix B.

2. How Was This Proposal Developed?

In 2000, EPA published the Public Notification Rule (65 FR 25982, May 4, 2000) (USEPA 2000d), which revised the general public notification regulations for public water systems in order to implement the public notification requirements of the 1996 SDWA amendments. This regulation established the requirements that public water systems must follow regarding the form, manner, frequency, and content of a public notice. Public notification of violations is an integral part of the public health protection and consumer right-to-know provisions of the 1996 SDWA Amendments.

Owners and operators of public water systems are required to notify persons served when they fail to comply with the requirements of a NPDWR, have a variance or exemption from the drinking water regulations, or are facing other situations posing a risk to public health. The public notification requirements divide violations into three categories (Tier 1, Tier 2 and Tier 3) based on the seriousness of the violations, with each tier having different public notification requirements.

EPA has limited its list of violations and situations routinely requiring a Tier 1 notice to those with a significant potential for serious adverse health effects from short term exposure. Tier 1 violations contain language specified by EPA that concisely and in non-technical terms conveys to the public the adverse health effects that may occur as a result of the violation. States and water utilities may add additional information to each notice, as deemed appropriate for specific situations. A State may elevate to Tier 1 other violations and situations with significant potential to have serious adverse health effects from short-term exposure, as determined by the State.

Tier 2 public notices address other violations with potential to have serious adverse health effects on human health. Tier 2 notices are required for the following situations:

- All violations of the MCL, maximum residual disinfectant level (MRDL) and treatment technique requirements, except where a Tier 1 notice is required or where the State determines that a Tier 1 notice is required; and
- Failure to comply with the terms and conditions of any existing variance or exemption.

Tier 3 public notices include all other violations and situations requiring public notice, including the following situations:

- A monitoring or testing procedure violation, except where a Tier 1 or 2 notice is already required or where the State has elevated the notice to Tier 1 or 2; and
- Operation under a variance or exemption.

The State, at its discretion, may elevate the notice requirement for specific monitoring or testing procedures from a Tier 3 to a Tier 2 notice, taking into account the potential health impacts and persistence of the violation.

As part of the IESWTR, EPA established health effects language for violations of treatment technique requirements for microbiological contaminants. EPA believes this language, which was developed with consideration of *Cryptosporidium* health effects, is appropriate for violations of additional *Cryptosporidium* treatment requirements under the LT2ESWTR.

3. Request for Comment

EPA requests comment on whether the violations of additional treatment requirements for *Cryptosporidium* under the LT2ESWTR should require a Tier 2 public notice and whether the proposed health effects language is appropriate.

H. Variances and Exemptions

SDWA section 1415 allows States to grant variances from national primary drinking water regulations under certain conditions; section 1416 establishes the conditions under which States may grant exemptions to MCL or treatment technique requirements. For the reasons presented in the following discussion, EPA has determined that systems will not be eligible for variances or exemptions to the requirements of the LT2ESWTR.

1. Variances

Section 1415 specifies two provisions under which general variances to treatment technique requirements may be granted:

(1) A State that has primacy may grant a variance to a system from any requirement to use a specified treatment technique for a contaminant if the system demonstrates to the satisfaction of the State that the treatment technique is not necessary to protect public health because of the nature of the system's raw water source. EPA may prescribe monitoring and other requirements as conditions of the variance (section 1415(a)(1)(B)).

(2) EPA may grant a variance from any treatment technique requirement upon a showing by any person that an alternative treatment technique not included in such requirement is at least as efficient in lowering the level of the contaminant (section 1415(a)(3)).

EPA does not believe the first provision for granting a variance is applicable to the LT2ESWTR because *Cryptosporidium* treatment technique requirements under this rule account for the degree of source water contamination. Systems initially comply with the LT2ESWTR by conducting source water monitoring for *Cryptosporidium*. Filtered systems are required to provide additional treatment for *Cryptosporidium* only if the source water concentration exceeds a level where current treatment does not provide sufficient protection. All unfiltered systems are required to provide a baseline of 2 log inactivation of *Cryptosporidium* to achieve finished water risk levels comparable to filtered systems; however, unfiltered systems are required to achieve 3 log inactivation only if the source water level exceeds 0.01 oocysts/L.

The second provision for granting a variance is not applicable to the LT2ESWTR because the treatment technique requirements of this rule specify the degree to which systems must lower their source water *Cryptosporidium* level (*e.g.*, 4, 5, and 5.5 log reduction in Bins 2, 3, and 4, respectively). The LT2ESWTR provides broad flexibility in how systems achieve the required level of *Cryptosporidium* reduction, as shown in the discussion of the microbial toolbox in section VI.C Moreover, the microbial toolbox contains an option for Demonstration of Performance, under which States can award treatment credit based on the demonstrated efficiency of a treatment process in reducing *Cryptosporidium* levels. Thus, there is no need for this type of variance under the LT2ESWTR.

SDWA section 1415(e) describes small system variances, but these cannot be granted for a treatment technique for a microbial contaminant. Hence, small system variances are not allowed for the LT2ESWTR.

2. Exemptions

Under SDWA section 1416(a), a State may exempt any public water system from a treatment technique requirement upon a finding that (1) due to compelling factors (which may include economic factors such as qualification of the system as serving a disadvantaged community), the system is unable to comply with the requirement or implement measures to develop an alternative source of water supply; (2) the system was in operation on the effective date of the treatment technique requirement, or for a system that was not in operation by that date, no

reasonable alternative source of drinking water is available to the new system; (3) the exemption will not result in an unreasonable risk to health; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A), the schedule shall require compliance as expeditiously as practicable (to be determined by the State), but no later than three years after the otherwise applicable compliance date for the regulations established pursuant to section 1412(b)(10). For public water systems that do not serve more than a population of 3,300 and that need financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of six years.

A public water system shall not be granted an exemption unless it can establish that: (1) The system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); or (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance pursuant to section 1452 or any other Federal or state program; or (3) the system has entered into an enforceable agreement to become part of a regional public water system.

EPA believes that granting an exemption to the *Cryptosporidium* treatment requirements of the LT2ESWTR would result in an unreasonable risk to health. As described in section II.C, *Cryptosporidium* causes acute health effects, which may be severe in sensitive subpopulations and include risk of mortality. Moreover, the additional *Cryptosporidium* treatment requirements of the LT2ESWTR are targeted to systems with the highest degree of risk. Due to these factors, EPA is not proposing to allow exemptions under the LT2ESWTR.

3. Request for Comment

a. *Variances.* EPA requests comment on the determination that the provisions for granting variances are not applicable to the proposed LT2ESWTR, specifically including *Cryptosporidium* inactivation requirements for unfiltered systems.

In theory it would be possible for an unfiltered system to demonstrate raw water *Cryptosporidium* levels that were 3 log lower than the cutoff for bin 1 for filtered systems and, thus, that it may be providing comparable public health protection without additional inactivation. However, EPA has determined that in practice it is not currently economically or technologically feasible for systems to ascertain the level of *Cryptosporidium* at this concentration. This is due to the extremely large number and volume of samples that would be necessary to make this demonstration with sufficient confidence. Based on this determination and the *Cryptosporidium* occurrence data described in section III.C, EPA is not proposing to allow unfiltered systems to demonstrate raw water *Cryptosporidium* levels low enough to avoid inactivation requirements. EPA requests comment on this approach.

b. *Exemptions.* EPA requests comment on the determination that granting an exemption to the *Cryptosporidium* treatment requirements of the LT2ESWTR would result in an unreasonable risk to health.

I. Requirements for Systems To Use Qualified Operators

The SWTR established a requirement that each public water system using a surface water source or a ground water source under the direct influence of surface water must be operated by qualified personnel who meet the requirements specified by the State (40 CFR 141.70). The Stage 1 DBPR extended this requirement to include all systems affected by that rule, and required that States maintain a register of qualified operators (40 CFR 141.130(c)). While the proposed LT2ESWTR establishes no new requirements regarding the operation of systems by qualified personnel, the Agency would like to emphasize the important role that qualified operators play in delivering safe drinking water to the public. EPA encourages States that do not already have operator certification programs in effect to develop such programs. States should also review and modify, as required, their qualification standards to take into account new technologies (*e.g.*, ultraviolet disinfection) and new compliance requirements.

J. System Reporting and Recordkeeping Requirements

1. Overview

Today's proposal includes reporting and recordkeeping requirements associated with proposed monitoring and treatment requirements. As described earlier, systems must conduct source water monitoring to determine a treatment bin classification for filtered systems or a mean *Cryptosporidium* level for unfiltered systems. Systems with previously collected monitoring data may be able to use (*i.e.*, grandfather) those data in lieu of conducting new monitoring. Following source water monitoring, systems will be required to comply with any additional *Cryptosporidium* treatment requirements by implementing treatment and control strategies from a microbial toolbox of options. Systems must conduct a second round of source water monitoring six years after bin classification.

In addition, systems using uncovered finished water storage facilities must cover the facility or provide treatment unless the system implements a State-approved risk management strategy. Certain systems will be required to conduct disinfection profiling and benchmarking.

The proposed rule requires public water systems to submit schedules for *Cryptosporidium*, *E. coli*, and turbidity sampling at least 3 months before monitoring must begin. Source water sample analysis results must be reported not later than ten days after the end of first month following the month when the sample is collected. As described later, large systems (at least 10,000 people served) will report monitoring results from the initial round of monitoring directly to EPA through an electronic data system. Small systems will report monitoring results to the State. Both small and large systems will report monitoring results from the second round of monitoring to the State.

Systems must report a bin classification (filtered systems) or mean *Cryptosporidium* level (unfiltered systems) within six months following the month when the last sample in a particular round of monitoring is scheduled to be collected. If systems are required to provide additional treatment for *Cryptosporidium*, they must report regarding the use of microbial toolbox components. Systems must notify the State within 24 months following promulgation of the rule if they use uncovered finished water storage facilities. Systems must also make reports related to disinfection profiling and benchmarking. Reporting

requirements associated with these activities are summarized in Tables IV–25 to IV–28.

TABLE IV–25.— SUMMARY OF INITIAL LARGE FILTERED SYSTEM REPORTING REQUIREMENTS

You must report the following items	On the following schedule
Sampling schedule for *Cryptosporidium*, *E. coli*, and turbidity monitoring.	No later than 3 months after promulgation.
Results of *Cryptosporidium*, *E. coli*, and turbidity analyses	No later than 10 days after the end of the first month following the month in which the sample is collected.
Bin determination	No later than 36 months after promulgation.
Demonstration of compliance with additional treatment requirements.	Beginning 72 months after promulgation [1] (See table IV–34).
Disinfection profiling component reports	See Table IV–35.

[1] States may grant an additional two years for systems making capital improvements.

TABLE IV–26.—SUMMARY OF INITIAL SMALL FILTERED SYSTEM REPORTING REQUIREMENTS

You must report the following items	On the following schedule
Sampling schedule for *E. coli* monitoring	No later than 27 months after promulgation.
Results of *E. coli* analyses (unless State approves a different indicator).	No later than 10 days after the end of the first month following the month in which the sample was collected.
Mean *E. coli* concentration (unless State approves a different indicator).	No later than 45 months after promulgation.
Disinfection profiling component reports	See Table IV–36.
Additional requirements if *E. coli* trigger level is exceeded [1]	
Sampling schedule for *Cryptosporidium* monitoring	No later than 45 months after promulgation.
Results of *Cryptosporidium* analyses	No later than 10 days after the end of the first month following the month in which the sample is collected.
Bin determination	No later than 66 months after promulgation.
Demonstration of compliance with additional treatment requirements.	Beginning 102 months after promulgation [2] (See Table IV–34).

[1] If the *E. coli* annual mean concentration exceeds 10/100 mL for systems using lakes/reservoirs or exceeds 50/100 mL for systems using flowing streams, then systems must conduct *Cryptosporidium* monitoring. States may approve alternative indicator criteria to trigger *Cryptosporidium* monitoring.
[2] States may grant an additional two years for systems making capital improvements.

TABLE IV–27.—SUMMARY OF INITIAL LARGE UNFILTERED SYSTEM REPORTING REQUIREMENTS

You must report the following items	On the following schedule
Cryptosporidium sampling schedule	No later than 3 months after promulgation.
Results of *Cryptosporidium* analyses	No later than 10 days after the end of the first month following the month in which the sample was collected.
Determination of mean *Cryptosporidium* concentration	No later than 36 months after promulgation.
Disinfection profiling component reports	See Table IV–35.
Demonstration of compliance with *Cryptosporidium* inactivation requirements.	Beginning 72 months after promulgation [1] (see Table IV–34).

[1] States may grant an additional two years for systems making capital improvements.

TABLE IV–28.—SUMMARY OF INITIAL SMALL UNFILTERED SYSTEM REPORTING REQUIREMENTS

You must report the following items	On the following schedule
Cryptosporidium sampling schedule	No later than 45 months after promulgation.
Results of *Cryptosporidium* analyses	No later than 10 days after the end of the first month following the month in which the sample was collected.
Determination of mean *Cryptosporidium* concentration	No later than 66 months after promulgation.
Disinfection profiling component reports	See Table IV–35.
Demonstration of compliance with *Cryptosporidium* inactivation requirements.	Beginning 102 months after promulgation [1] (see Table IV–34).

[1] States may grant an additional two years for systems making capital improvements.

2. Reporting Requirements for Source Water Monitoring

a. *Data elements to be reported.* Proposed reporting requirements for LT2ESWTR monitoring stem from proposed analytical method requirements. As stated in sections IV.K and IV.L, systems must have *Cryptosporidium* analyses conducted by EPA-approved laboratories using Methods 1622 or 1623. *E. coli* analyses must be performed by State-approved laboratories using the *E. coli* methods proposed for approval in section IV.K. Systems are required to report the data elements specified in Table IV–29 for each *Cryptosporidium* analysis. To comply with LT2ESWTR requirements, only the sample volume filtered and the number of oocysts counted must be reported for samples in which at least 10 L is filtered and all of the sample volume is analyzed. Additional information is required for samples where the laboratory analyzes less than 10 L or less than the full sample volume collected. Table IV–30 presents the data elements that systems must report for *E. coli* analyses.

As described in the following section, EPA is developing a data system to manage and analyze the microbial monitoring data that will be reported by large systems under the LT2ESWTR. EPA is exploring approaches for application of this data system to support small system data reporting as well. Systems, or laboratories acting as the systems' agents, must keep Method 1622/1623 bench sheets and slide examination report forms until 36 months after an equivalent round of source water monitoring has been completed (*e.g.*, second round of *Cryptosporidium* monitoring).

TABLE IV–29.—PROPOSED *Cryptosporidium* DATA ELEMENTS TO BE REPORTED

Data element	Reason for data element
Identifying information	
• PWSID	Needed to associate plant with public water system.
• Facility ID	Needed to associate sample result with facility.
• Sample collection point	Needed to associate sample result with sampling point.
• Sample collection date	Needed to determine that utilities are collecting samples at the frequency required.
• Sample type (field or matrix spike) [1]	Needed to distinguish field samples from matrix samples for recovery calculations.
Sample results	
• Sample volume filtered (L), to nearest ¼ L [2]	Needed to verify compliance with sample volume requirements.
• Was 100% of filtered volume examined? [3]	Needed to calculate the final concentration of oocysts/L and determine if volume analyzed requirements are met.
• Number of oocysts counted	Needed to calculate the final concentration of oocysts/L.

[1] For matrix spike samples, sample volume spiked and estimated number of oocysts spiked must be reported. These data are not required for field samples.

[2] For samples in which <10 L is filtered or <100% of the sample volume is examined, the number of filters used and the packed pellet volume must also be reported to verify compliance with LT2ESWTR sample volume analysis requirements. These data are not required for most samples.

[3] For samples in which <100% of sample is examined, the volume of resuspended concentrate and volume of this resuspension processed through IMS must be reported to calculate the sample volume examined. These data will not be required for most samples.

TABLE IV–30.—PROPOSED *E. coli* DATA ELEMENTS TO BE REPORTED

Data element	Reason for collecting data element
Identifying Information	
PWS ID	Needed to associate analytical result with public water system.
Facility ID	Needed to associate plant with public water system.
Sample collection point	Needed to associate sample result with sampling point.
Sample collection date	Needed to determine that utilities are collecting samples at the frequency required.
Analytical method number	Needed to associate analytical result with analytical method.
Method Type	Needed to verify that an approved method was used and call up correct web entry form.
Source water type	Needed to assess *Cryptosporidium* indicator relationships.
E. coli/100 mL	Sample result (although not required, the laboratory also will have the option of entering primary measurements for a sample into the LT2ESWTR internet-based database to have the database automatically calculate the sample result).
Turbidity Information	
Turbidity result	Needed to assess *Cryptosporidium* indicator relationships.

b. Data system. Because source water monitoring by large systems (serving at least 10,000 people) will begin 6 months following promulgation of the LT2ESWTR, EPA expects to act as the primacy agency with oversight responsibility for large system sampling, analysis, and data reporting. To facilitate collection and analysis of large system monitoring data, EPA is developing an Internet-based electronic data collection and management system. This approach is similar to that used under the Unregulated Contaminants Monitoring Rule (UCMR) (64 FR 50556, September 17, 1999) (USEPA 1999c).

Analytical results for *Cryptosporidium*, *E. coli*, and turbidity analyses will be reported directly to this database using web forms and software that can be downloaded free of charge.

The data system will perform logic checks on data entered and calculate final results from primary data (where necessary). This is intended to reduce reporting errors and limit the time involved in investigating, checking, and correcting errors at all levels. EPA will make large system monitoring data available to States when States assume primacy for the LT2ESWTR or earlier under State agreements with EPA.

Large systems should instruct their laboratories to electronically enter monitoring results into the EPA data system using web-based manual entry forms or by uploading XML files from laboratory information management systems (LIMS). After data are submitted by a laboratory, systems may review the results on-line. If a system believes that a result was entered into the data system erroneously, the system may notify the laboratory to rectify the entry. In addition, if a system believes that a result is incorrect, the system may submit the result as a contested result and petition EPA or the State to invalidate the sample. If a system contests a sample result, the system must submit a rationale to the primacy agency, including a supporting statement from the laboratory, providing a justification. Systems may arrange with laboratories to review their sample results prior to the results being entered into the EPA data system. Also, if a system determines that its laboratory does not have the capability to report data electronically, the system can submit a request to EPA to use an alternate reporting format.

Regardless of the reporting process used, systems are required to report an analytical monitoring result to the primacy agency no later than 10 days after the end of the first month following the month when the sample was collected. As described in section IV.A.1, if a system is unable to report a valid *Cryptosporidium* analytical result for a scheduled sampling date due to failure to comply with the analytical method requirements (*e.g.*, violation of quality control requirements), the system must collect a replacement sample within 14 days of being notified by the laboratory or the State that a result cannot be reported for that date and must submit an explanation for the replacement sample with the analytical results. A system will not incur a monitoring violation if the State determines that the failure to report a valid analysis result was due to circumstances beyond the control of the system. However, in all cases the system must collect a replacement sample.

The data elements to be collected by the electronic data system will enhance the reliability of the microbial data generated under the LT2ESWTR, while reducing the burden on the analytical laboratories and public water systems. Tables IV–31 and IV–32 summarize the system's data analysis functions for *Cryptosporidium* measurements.

TABLE IV–31.— LT2ESWTR DATA SYSTEM FUNCTIONS FOR *Cryptosporidium* DATA

Value calculated	Formula	Applicability to sample types	
		Field	Matrix spike
Calculation of sample volume analyzed.	(Volume filtered) * (resuspended concentrate volume transferred to IMS/resuspended concentrate volume).	Yes	Yes.
Pellet volume analyzed	(pellet volume)*(resuspended concentrated volume transferred to IMS/resuspended concentrate volume).	Yes	Yes.
Calculation of oocysts/L	(Number of oocysts counted)/(sample volume analyzed)	Yes	Yes.
Calculation of estimated number of oocysts spiked/L.	(Number of oocysts spiked)/(sample volume spiked)	No	Yes.
Calculation of percent recoveries for MS samples.	((Calculated # of oocysts/L for the MS sample)—(Calculated # of oocysts/L in the associated field sample)) / (Estimated number of oocysts spiked/L) * 100%.	No	Yes.

TABLE IV–32.—LT2ESWTR DATA SYSTEM FUNCTIONS FOR *Cryptosporidium* COMPLIANCE CHECKS

LT2 requirements	Description
Sample volume analysis	Specifies that the LT2 requirements for sample volume analyzed were met when: • volume analyzed is > 10 L. • volume analyzed is < 10 L and pellet volume analyzed is at least 2 mL. • volume analyzed < 10 L and pellet volume analyzed < 2 mL and 100% of filtered volume examined= Y and two filters were used. Specifies that the LT2 requirements for sample volume analyzed were not met when: • volume analyzed < 10 L and pellet volume analyzed is < 2 mL and 100% of filtered volume examined= N. • volume analyzed is < 10 L and pellet volume analyzed < 2 mL and only 1 filter used.
Schedule met	Specifies that the predetermined sampling schedule is met when the sample collection data is within ± 2 days of the scheduled date.

c. *Previously collected monitoring data.* Table IV–33 provides a summary of the items that systems must report to EPA for consideration of previously collected (grandfathered) monitoring data under the LT2ESWTR. For each field and matrix spike (MS) sample, systems must report the data elements specified in Table IV–29. In addition, the laboratory that analyzed the samples must submit a letter certifying that all Method 1622 and 1623 quality control requirements (including ongoing precision and recovery (OPR) and method blank (MB) results, holding times, and positive and negative staining controls) were performed at the required frequency and were acceptable. Alternatively, the laboratory may provide for each field, MS, OPR, and MB sample a bench sheet and sample examination report form (Method 1622 and 1623 bench sheets are shown in USEPA 2003h).

Systems must report all routine source water *Cryptosporidium* monitoring results collected during the

period covered by the previously collected data that have been submitted. This applies to all samples that were collected from the sampling location used for monitoring, not spiked, and analyzed using the laboratory's routine process for Method 1622 or 1623 analyses, including analytical technique and QA/QC. Other requirements associated with use of previously collected data are specified in section IV.A.1.d. Where applicable, systems must provide documentation addressing the dates and reason(s) for re-sampling, as well as the use of presedimentation, off-stream storage, or bank filtration during monitoring. Review of the submitted information, along with the results of the quality assurance audits of the laboratory that produced the data, will be used to determine whether the data meet the requirements for grandfathering.

TABLE IV–33.—ITEMS THAT MUST BE REPORTED FOR CONSIDERATION OF GRANDFATHERED MONITORING DATA

The following items must be reported [1]	On the following schedule [1]
Data elements listed in Table IV–29 for each field and MS sample	No later than 2 months after promulgation if the system does not intend to conduct new monitoring under the LT2ESWTR.
Letter from laboratory certifying that method-specified QC was performed at required frequency and was acceptable. OR Method 1622/1623 bench sheet and sample examination report form for each field, MS, OPR, and method blank sample.	OR No later than 8 months after promulgation if the system intends to conduct new monitoring under the LT2ESWTR.
Letter from system certifying (1) that all source water data collected during the time period covered by the previously collected data have been submitted and (2) that the data represent the plant's current source water.	
Where applicable, documentation addressing the dates and reason(s) for re-sampling, as well as the use of presedimentation, off-stream storage, or bank filtration during monitoring.	

[1] See section IV.A.1. for details.

3. Compliance With Additional Treatment Requirements

Under the proposed LT2ESWTR, systems may choose from a ''toolbox'' of management and treatment options to meet their additional *Cryptosporidium* treatment requirements. In order to receive credit for toolbox components, systems must initially demonstrate that they comply with any required design and implementation criteria, including performance validation testing. Additionally, systems must provide monthly verification of compliance with any required operational criteria, as shown through ongoing monitoring. Required design, implementation, operational, and monitoring criteria for toolbox components are described in section IV.C. Proposed reporting requirements associated with these criteria are shown in Table IV–34 for both large and small systems.

TABLE IV–34.—TOOLBOX REPORTING REQUIREMENTS

Toolbox option (potential *Cryptosporidium* reduction log credit)	You must submit the following items	On the following schedule [1] (systems serving ≥10,000 people)	On the following schedule [1] (systems serving < 10,000 people)
Watershed Control Program (WCP) (0.5 log)	Notify State of intention to develop WCP	No later than 48 months after promulgation	No later than 78 months after promulgation.
	Submit initial WCP plan to State	No later than 60 months after promulgation	No later than 90 months after promulgation.
	Annual program status report and State-approved watershed survey report.	By a date determined by the State, every 12 months, beginning 84 months after promulgation	By a date determined by the State, every 12 months, beginning 114 months after promulgation.
	Request for re-approval and report on the previous approval period.	No later than 6 months prior to the end of the current approval period or by a date previously determined by the State	No later than 6 months prior to the end of the current approval period or by a date previously determined by the State.
Pre-sedimentation (0.5 log) (new basins)	Monthly verification of: Continuous basin operation Treatment of 100% of the flow Continuous addition of a coagulant At least 0.5 log removal of influent turbidity based on the monthly mean of daily turbidity readings for 11 of the 12 previous months	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning 72 months after promulgation	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning 102 months after promulgation.
Two-Stage Lime Softening (0.5 log)	Monthly verification of: Continuous operation of a second clarification step between the primary clarifier and filter Presence of coagulant (may be lime) in first and second stage clarifiers Both clarifiers treat 100% of the plant flow	No later than 72 months after promulgation	No later than 102 months after promulgation.

TABLE IV–34.—TOOLBOX REPORTING REQUIREMENTS—Continued

Toolbox option (potential *Cryptosporidium* reduction log credit)	You must submit the following items	On the following schedule [1] (systems serving ≥10,000 people)	On the following schedule [1] (systems serving < 10,000 people)
Bank filtration (0.5 or 1.0 log) (new)	Initial demonstration of: Unconsolidated, predominantly sandy aquifer Setback distance of at least 25 ft. (0.5 log) or 50 ft. (1.0 log) If monthly average of daily max turbidity is greater than 1 NTU then system must report result and submit an assessment of the cause	Initial demonstration no later than 72 months after promulgation Report within 30 days following the month in which the monitoring was conducted, beginning 72 months after promulgation	Initial demonstration no later than 102 months after promulgation. Report within 30 days following the month in which the monitoring was conducted, beginning 102 months after promulgation.
Combined filter performance (0.5 log)	Monthly verification of: Combined filter effluent (CFE) turbidity levels less than or equal to 0.15 NTU in at least 95 percent of the 4 hour CFE measurements taken each month	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on 72 months after promulgation	Monthly reporting: within 10 days following the month in which the monitoring was conducted, beginning on 102 months after promulgation.
Membranes (MF, UF, NF, RO) (2.5 log or greater based on verification/integrity testing)	Initial demonstration of: Removal efficiency through challenge studies Methods of challenge studies meet rule criteria Integrity test results and baseline	No later than 72 months after promulgation	No later than 102 months after promulgation.
	Monthly report summarizing: All direct integrity test results above the control limit and the corrective action that was taken All indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation.
Bag filters (1.0 log) and Cartridge filters (2.0 log)	Initial demonstration that the following criteria are met: Process meets the basic definition of bag or cartridge filtration; Removal efficiency established through challenge testing that meets rule criteria Challenge test shows at least 2 and 3 log removal for bag and cartridge filters, respectively	No later than 72 months after promulgation	No later than 102 months after promulgation.
Chlorine dioxide (log credit based on CT)	Summary of CT values for each day and log inactivation based on tables in section IV.C.14	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation.
Ozone (log credit based on CT)	Summary of CT values for each day and log inactivation based on tables in section IV.C.14	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation.
UV (log credit based UV dose and operating within validated conditions)	Results from reactor validation testing demonstrating operating conditions that achieve required UV dose	No later than 72 months after promulgation	No later than 102 months after promulgation.
	Monthly report summarizing the percentage of water entering the distribution system that was not treated by UV reactors operating within validated conditions for the required UV dose in section IV.C.15	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation.
Individual filter performance (1.0 log)	Monthly verification of the following, based on continuous monitoring of turbidity for each individual filter: Filtered water turbidity less than 0.1 NTU in at least 95 percent of the daily maximum values from individual filters (excluding 15 minute period following start up after backwashes) No individual filter with a measured turbidity greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on 72 months after promulgation	Monthly reporting: within 10 days following the month in which the monitoring was conducted, beginning 102 months after promulgation.
Demonstration of Performance	Results from testing following State approved protocol	No later than 72 months after promulgation	No later than 102 months after promulgation.

TABLE IV–34.—TOOLBOX REPORTING REQUIREMENTS—Continued

Toolbox option (potential *Cryptosporidium* reduction log credit)	You must submit the following items	On the following schedule [1] (systems serving ≥10,000 people)	On the following schedule [1] (systems serving < 10,000 people)
	Monthly verification of operation within State-approved conditions for demonstration of performance credit	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation.

[1] States may allow an additional two years for systems making capital improvements.

Reporting requirements associated with disinfection profiling and benchmarking are summarized in Table IV–35 for large systems and in Table IV–36 for small systems.

TABLE IV–35.—DISINFECTION BENCHMARKING REPORTING REQUIREMENTS FOR LARGE SYSTEMS

System type	Benchmark component	Submit the following items	On the following schedule
Systems required to conduct *Cryptosporidium* monitoring.	Characterization of Disinfection Practices	*Giardia lamblia* and virus inactivation profiles must be on file for State review during sanitary survey.	No later than 36 months after promulgation.
	State Review of Proposed Changes to Disinfection Practices.	Inactivation profiles and benchmark determinations.	Prior to significant modification of disinfection practice.
Systems not required to conduct *Cryptosporidium* monitoring[1].	Applicability	None	None.
	Characterization of Disinfection Practices	None	None.
	State Review of Proposed Changes to Disinfection Practices.	None	None.

[1]Systems that provide at least 5.5 log of *Cryptosporidium* treatment consistent with a Bin 4 treatment implication are not required to conduct *Cryptosporidium* monitoring.

TABLE IV–36.—DISINFECTION BENCHMARKING REPORTING REQUIREMENTS FOR SMALL SYSTEMS

System type	Benchmark component	Submit the following items	On the following schedule
Systems required to conduct *Cryptosporidium* monitoring.	Characterization of Disinfection Practices	*Giardia lamblia* and virus inactivation profiles must be on file for State review during sanitary survey.	No later than 66 months after promulgation.
	State Review of Proposed Changes to Disinfection Practices.	Inactivation profiles and benchmark determinations.	Prior to significant modification of disinfection practice.
Systems not required to conduct *Cryptosporidium* monitoring and that exceed DBP triggers[1,2,3].	Applicability Period	Notify State that profiling is required based on DBP levels.	No later than 42 months after promulgation.
	Characterization of Disinfection Practices	*Giardia lamblia* and virus inactivation profiles must be on file for State review during sanitary survey.	No later than 54 months after promulgation.
	State Review of Proposed Changes to Disinfection Practices.	Inactivation profiles and benchmark determinations.	Prior to significant modification of disinfection practice.
Systems not required to conduct *Cryptosporidium* monitoring and that do not exceed DBP triggers[2,3].	Applicability Period	Notify State that profiling is not required based on DBP levels.	No later than 42 months after promulgation.
	Characterization of Disinfection Practices	None	None.
	State Review of Proposed Changes to Disinfection Practices.	None	None.

[1] Systems that provide at least 5.5 log of *Cryptosporidium* treatment consistent with a Bin 4 treatment implication are not required to conduct *Cryptosporidium* monitoring.

[2] If the *E. coli* annual mean concentration is ≤ 10/100 mL for systems using lakes/reservoir sources or ≤ 50/100 mL for systems using flowing stream sources, the system is not required to conduct *Cryptosporidium* monitoring and will only be required to characterize disinfection practices if DBP triggers are exceeded.

[3] If the system is a CWS or NTNCWSs and TTHM or HAA5 levels in the distribution system are at least 0.064 mg/L or 0.048 mg/L, respectively, calculated as an LRAA at any Stage 1 DBPR sampling site, then the system is triggered into disinfection profiling.

4. Request for Comment

EPA requests comment on the reporting and recordkeeping requirements proposed for the LT2ESWTR.

Specifically, the Agency requests comment on the proposed requirement that systems report monthly on the use of microbial toolbox components to demonstrate compliance with their *Cryptosporidium* treatment requirements. An alternative may be for systems to keep records on site for State review instead of reporting the data.

K. Analytical Methods

EPA is proposing to require public water systems to conduct LT2ESWTR monitoring using approved methods for *Cryptosporidium*, *E. coli*, and turbidity analyses. This includes meeting quality control criteria stipulated by the approved methods and additional method-specific requirements, as stated later in this section. Related requirements on the use of approved laboratories are discussed in section IV.L, and proposed requirements for reporting of data were stated previously in section IV.J. EPA has developed draft guidance for sampling and analyses under the LT2ESWTR (see USEPA 2003g and 2003h). This guidance is available in draft form in the docket for today's proposal (*http://www.epa.gov/edocket/*).

1. *Cryptosporidium*

a. *What is EPA proposing today?* Method 1622: ''*Cryptosporidium* in Water by Filtration/IMS/FA'' (EPA–821-R–01–026, April 2001) (USEPA 2001e) and Method 1623: ''*Cryptosporidium* and Giardia in Water by Filtration/IMS/FA'' (EPA 821–R–01–025, April 2001) (USEPA 2001f) are proposed for *Cryptosporidium* analysis under this rule. Methods 1622 and 1623 require filtration, immunomagnetic separation (IMS) of the oocysts from the captured material, and examination based on IFA, DAPI staining results, and differential interference contrast (DIC) microscopy for determination of oocyst concentrations.

Method Requirements

For each *Cryptosporidium* sample under this proposal, all systems must analyze at least a 10–L sample volume. Systems may collect and analyze greater than a 10–L sample volume. If a sample is very turbid, it may generate a large packed pellet volume upon centrifugation (a packed pellet refers to the concentrated sample after centrifugation has been performed in EPA Methods 1622 and 1623). Based on IMS purification limitations, samples resulting in large packed pellets will require that the sample concentrate be aliquoted into multiple ''subsamples'' for independent processing through IMS, staining, and examination. Because of the expense of the IMS reagents and analyst time to examine multiple slides per sample, systems are not required to analyze more than 2 mL of packed pellet volume per sample.

In cases where it is not feasible for a system to process a 10–L sample for *Cryptosporidium* analysis (*e.g.*, filter clogs prior to filtration of 10 L) the system must analyze as much sample volume as can be filtered by 2 filters, up to a packed pellet volume of 2 mL. This condition applies only to filters that have been approved by EPA for nationwide use with Methods 1622 and 1623—the Pall Gelman Envirochek™ and Envirochek™ HV filters, the IDEXX Filta-Max™ foam filter, and the Whatman CrypTest™ cartridge filter.

Methods 1622 and 1623 include fluorescein isothiocyanate (FITC) as the primary antibody stain for *Cryptosporidium* detection, DAPI staining to detect nuclei, and DIC to detect internal structures. For purposes of the LT2ESWTR, systems must report total *Cryptosporidium* oocysts as detected by FITC as determined by the color (apple green or alternative stain color approved for the laboratory under the Lab QA Program described in section VI.L), size (4–6 μm) and shape (round to oval). This total includes all of the oocysts identified as described here, less atypical organisms identified by FITC, DIC, or DAPI (*e.g.*, possessing spikes, stalks, appendages, pores, one or two large nuclei filling the cell, red fluorescing chloroplasts, crystals, spores, etc.).

Matrix Spike Samples

As required by Method 1622 and 1623, systems must have 1 matrix spike (MS) sample analyzed for each 20 source water samples. The volume of the MS sample must be within ten percent of the volume of the unspiked sample that is collected at the same time, and the samples must be collected by splitting the sample stream or collecting the samples sequentially. The MS sample and the associated unspiked sample must be analyzed by the same procedure. MS samples must be spiked and filtered in the laboratory. However, if the volume of the MS sample is greater than 10 L, the system is permitted to filter all but 10 L of the MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory. In this case, the laboratory must spike the remaining 10 L of water and filter it through the filter used to collect the balance of the sample in the field.

EPA is proposing to require the use of flow cytometer-counted spiking suspensions for spiked QC samples during the LT2ESWTR. This provision is based on the improved precision expected for spiking suspensions counted with a flow cytometer, as compared to those counted using well slides or hemacytometers. During the Information Collection Rule Supplemental Surveys, the mean relative standard deviation (RSD) across 25 batches of flow cytometer-sorted *Cryptosporidium* spiking suspensions was 1.8%, with a median of 1.7% (Connell *et al.* 2000). In EPA Performance Evaluation (PE) studies, the mean RSD for flow cytometer sorted *Cryptosporidium* spiking suspensions was 3.4%. In comparison, the mean RSD for *Cryptosporidium* spiking suspensions enumerated manually by 20 laboratories using well slides or hemacytometers was 17% across 108 rounds of 10-replicate counts.

QC requirements in Methods 1622 and 1623 must be met by laboratories analyzing *Cryptosporidium* samples under the LT2ESWTR. The QC acceptance criteria are the same as stipulated in the method. For the initial precision and recovery (IPR) test, the mean *Cryptosporidium* recovery must be 24% to 100% with maximum relative standard deviation (*i.e.*, precision) of 55%. For each ongoing precision and recovery (OPR) sample, recovery must be in the range of 11% to 100%. For each method blank, oocysts must be undetected.

Methods 1622 and 1623 are performance-based methods and, therefore, allow multiple options to perform the sample processing steps in the methods if a laboratory can meet applicable QC criteria and uses the same determinative technique. If a laboratory uses the same procedures for all samples, then all field samples and QC samples must be analyzed in that same manner. However, if a laboratory uses more than one set of procedures for *Cryptosporidium* analyses under LT2ESWTR then the laboratory must analyze separate QC samples for each

option to verify compliance with the QC criteria. For example, if the laboratory analyzes samples using both the Envirochek™ and Filta-Max™ filters, a separate set of IPR, OPR, method blank, and MS samples must be analyzed for each filtration option.

b. *How was this proposal developed?* EPA is proposing EPA Methods 1622 and 1623 for *Cryptosporidium* analyses under the LT2ESWTR because these are the best available methods that have undergone full validation testing. In addition, these methods have been used successfully in a national source water monitoring program as part of the Information Collection Rule Supplemental Surveys (ICRSS). The minimum sample volume and other quality control requirements are intended to ensure that data are of sufficient quality to assign systems to LT2ESWTR risk bins. Further, the proposed method requirements for analysis of *Cryptosporidium* are consistent with recommendations by the Stage 2 M-DBP Advisory Committee. In the Agreement in Principle, the Committee recommended that source water *Cryptosporidium* monitoring under the LT2ESWTR be conducted using EPA Methods 1622 and 1623 with no less than 10 L samples. EPA also has proposed these methods for approval for ambient water monitoring under Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water (66 FR 45811, August 30, 2001) (USEPA 2001i).

When considering the method performance that could be achieved for analysis of *Cryptosporidium* under the LT2ESWTR, EPA and the Advisory Committee evaluated the *Cryptosporidium* recoveries reported for Methods 1622 and 1623 in the ICRSS. As described in section III.C, the ICRSS was a national monitoring program that involved 87 utilities sampling twice per month over 1 year for *Cryptosporidium* and other microorganisms and water quality parameters. During the ICRSS, the mean recovery and relative standard deviation associated with enumeration of MS samples for total oocysts by Methods 1622 and 1623 were 43% and 47%, respectively (Connell *et al.* 2000).

EPA believes that with provisions like the Laboratory QA Program for *Cryptosporidium* laboratories (see section IV.L), comparable performance to that observed in the ICRSS can be achieved in LT2ESWTR monitoring with the use of Methods 1622 and 1623, and that this level of performance will be sufficient to realize the public health goals intended by EPA and the Advisory Committee for the LT2ESWTR. Other methods would need to achieve comparable performance to be considered for use under the LT2ESWTR. For example, EPA does not expect the Information Collection Rule Method, which resulted in 12% mean recovery for MS samples during the Information Collection Rule Laboratory Spiking Program (Scheller, 2002), to meet LT2ESWTR data quality objectives.

For systems collecting samples larger than 10 L, EPA is proposing the approach of allowing systems to filter all but 10 L of the corresponding MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory for spiking and analysis. The Agency has determined that the added costs associated with shipping entire high-volume (*e.g.* 50–L) samples to a laboratory for spiking and analysis are not merited by improved data quality relative to the use of *Cryptosporidium* MS data under the LT2ESWTR. EPA estimates that the average cost for shipping a 50–L bulk water sample is $350 more than the cost of shipping a 10–L sample and a filter. A study comparing these two approaches (*i.e.*, spiking and filtering 50 L vs. field filtering 40 L and spiking 10 L) indicated that spiking the 10–L sample produced somewhat higher recoveries (USEPA 2003i). However, the differences were not significant enough to offset the greatly increased shipping costs, given the limited use of MS data in LT2ESWTR monitoring.

c. *Request for comment.* EPA requests comment on the proposed method requirements for *Cryptosporidium* analysis, including the following specific issues:

Minimum Sample Volume

It is the intent of EPA that LT2ESWTR sampling provide representative annual mean source water concentrations. If systems were unable to analyze an entire sample volume during certain periods of the year due to elevated turbidity or other water quality factors, this could result in systems analyzing different volumes in different samples. Today's proposal requires systems to analyze at least 10 L of sample or the maximum amount of sample that can be filtered through two filters, up to a packed pellet volume of 2 mL. EPA requests comment on whether these requirements are appropriate for systems with source waters that are difficult to filter or that generate a large packed pellet volume. Alternatively, systems could be required to filter and analyze at least 10 L of sample with no exceptions.

Approval of Updated Versions of EPA Methods 1622 and 1623

EPA has developed draft revised versions of EPA Methods 1622 and 1623 in order to consolidate several method-related changes EPA believes may be necessary to address LT2ESWTR monitoring requirements (see USEPA 2003j and USEPA 2003k). EPA is requesting comment on whether these revised versions should be approved for monitoring under the LT2ESWTR, rather than the April 2001 versions proposed in today's rule. If the revised versions were approved, previously collected data generated using the earlier versions of the methods would still be acceptable for grandfathering, provided the other criteria described in section IV.A.1.d were met. Drafts of the updated methods are provided in the docket for today's rule, and differences between these versions and the April 2001 versions of the methods are clearly indicated for evaluation and comment. Changes to the methods include the following:

(1) Increased flexibility in matrix spike (MS) and initial precision and recovery (IPR) requirements—the requirement that the laboratory must analyze an MS sample on the first sampling event for a new PWS would be changed to a recommendation; the revised method would allow the IPR test to be performed across four different days, rather than restrict analyses to 1 day;

(2) Clarification of some method procedures, including the spiking suspension vortexing procedure and the buffer volumes used during immunomagnetic separation (IMS); requiring (rather than recommending) that laboratories purchase HCl and NaOH standards at the normality specified in the method; and clarification that the use of methanol during slide staining in section 14.2 of the method is as per manufacturer's instructions;

(3) Additional recommendations for minimizing carry-over of debris onto microscope slides after IMS and information on microscope cleaning;

(4) Clarification in the method of the actions to take in the event of QC failures, such as that any positive sample in a batch associated with an unacceptable method blank is unacceptable and that any sample in a batch associated with an unacceptable ongoing precision and recovery (OPR) sample is unacceptable;

(5) Changes to the sample storage and shipping temperature to ''less than 10°C and not frozen'', and additional guidance on sample storage and shipping procedures that addresses time of collection, and includes suggestions for monitoring sample temperature during shipment and upon receipt at the laboratory.

(6) Additional analyst verification procedures—adding examination using differential interference contrast (DIC) microscopy to the analyst verification requirements.

(7) Addition of an approved method modification using the Pall Gelman Envirochek HV filter. This approval was based on an interlaboratory validation study demonstrating that three laboratories, each analyzing reagent water and a different source water, met all method acceptance criteria for *Cryptosporidium*. EPA issued a letter (dated March 21, 2002) under the Alternative Test Procedures program approving the procedure as an acceptable version of Method 1623 for *Cryptosporidium* (but not for Giardia). EPA also noted in the letter that the procedure was considered to be an acceptable modification of EPA Method 1622.

(8) Incorporation of detailed procedures for concentrating samples using an IDEXX Filta-Max™ foam filter. A method modification using this filter already is approved by EPA in the April 2001 versions of the methods.

(9) Addition of BTF EasySeed™ irradiated oocysts and cysts as acceptable materials for spiking routine QC samples. EPA approved the use of EasySeed™ based on side-by-side comparison tests of method recoveries using EasySeed™ and live, untreated organisms. EPA issued a letter (dated August 1, 2002) approving EasySeed™ for use in routine QC samples for EPA Methods 1622 and 1623 and for demonstrating comparability of method modifications in a single laboratory.

(10) Removal of the Whatman Nuclepore CrypTest™ cartridge filter. Although a method modification using this filter was approved by EPA in the April 2001 versions of the methods, the filter is no longer available from the manufacturer, and so is no longer an option for sample filtration.

The changes in the June 2003 draft revisions of EPA Methods 1622 and 1623 reflect method-related clarifications, modifications, and additions that EPA believes should be addressed for LT2ESWTR *Cryptosporidium* monitoring. Alternatively, these issues could be addressed through regulatory requirements in the final LT2ESWTR (for required changes and additions) and through guidance (for recommended changes and clarifications). However, EPA believes that addressing these issues through a single source in updated versions of EPA Methods 1622 and 1623 (which could be approved in the final LT2ESWTR) may be more straightforward and easier for systems and laboratories to follow than addressing them in multiple sources (*i.e.*, existing methods, the final rule, and laboratory guidance).

2. *E. coli*

a. *What is EPA proposing today?* For enumerating source water *E. coli* density under the LT2ESWTR, EPA is proposing to approve the same methods that were proposed by EPA under Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water (66 FR 45811, August 30, 2001) (USEPA 2001i). These methods are summarized in Table IV–37. Methods are listed within the general categories of most probable number tests and membrane filtration tests. Method identification numbers are provided for applicable standards published by EPA and voluntary consensus standards bodies (VCSB) including Standard Methods, American Society of Testing Materials (ASTM), and the Association of Analytical Chemists (AOAC).

TABLE IV–37.— PROPOSED METHODS FOR E. COLI ENUMERATION [1]

Technique	Method[1]	EPA	VCSB methods			Commercial example
			Standard methods[2]	ASTM[3]	AOAC[4]	
Most Probable Number (MPN).	LTB, EC-MUG		9221B.1/ 9221F			
	ONPG-MUG		9223B		991.15	Colilert®[5].
	ONPG-MUG		9223B			Colilert-18®[5 7].
Membrane Filter (MF) ..	mFC→NA–MUG		9222D/ 9222G			
	mENDO or LES-ENDO→NA–MUG.		9222B/ 9222G			
	mTEC agar	1103.1	9213D	D5392–93		
	Modified mTEC agar	1603				
	MI medium	1604				
	m-ColiBlue24 broth					m-ColiBlue24[6].

[1] Tests must be conducted in a format that provides organism enumeration.
[2] Standard Methods for the Examination of Water and Wastewater. American Public Health Association. 20th, 19th, and 18th Editions. Amer. Publ. Hlth. Assoc., Washington, DC.
[3] Annual Book of ASTM Standards—Water and Environmental Technology. Section 11.02. ASTM. 100 Barr Harbor Drive, West Conshohocken, PA 19428.
[4] Official Methods of Analysis of AOAC International, 16th Edition, Volume I, Chapter 17. AOAC International. 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877–2417.
[5] Manufactured by IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092.
[6] Manufactured by Hach Company, 100 Dayton Ave., Ames, IA 50010.
[7] Acceptable version of method approved as a drinking water alternative test procedure.

EPA is proposing to allow a holding time of 24 hours for *E. coli* samples. The holding time refers to the time between sample collection and initiation of analysis. Currently, 40 CFR 141.74(a) limits the holding time for source water coliform samples to 8 hours and requires that samples be kept below 10°C during transit. EPA believes that new studies, described later in this section, demonstrate that *E. coli* analysis results for samples held for 24 hours will be comparable to samples held for 8 hours, provided the samples are held below 10°C and are not allowed to freeze. This proposed increase in holding time is significant for the LT2ESWTR because typically it is not feasible for systems to meet an 8-hour holding time when samples cannot be analyzed on-site. Many small systems that will conduct *E. coli* monitoring under the LT2ESWTR lack a certified on-site laboratory for *E. coli* analyses and will be required to ship samples to a certified laboratory. EPA believes that it is feasible for these systems to comply with a 24 hour holding time for *E. coli* samples through using overnight delivery services.

b. *How was this proposal developed?* As noted, EPA recently proposed methods for ambient water *E. coli* analysis under Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for

Biological Pollutants in Ambient Water (66 FR 45811, August 30, 2001) (USEPA 2001i). These proposed methods were selected based on data generated by EPA laboratories, submissions to the alternate test procedures (ATP) program and voluntary consensus standards bodies, published peer reviewed journal articles, and publicly available study reports.

The source water analysis for *E. coli* that will be conducted under the LT2ESWTR is similar to the type of ambient water analyses for which these methods were previously proposed (66 FR 45811, August 30, 2001) (USEPA 2001i). EPA continues to support the findings of this earlier proposal and believes that these methods have the necessary sensitivity and specificity to meet the data quality objectives of the LT2ESWTR.

New Information on *E. coli* Sample Holding Time

It is generally not feasible for systems that must ship *E. coli* samples to an off-site laboratory to comply with an 8-hour holding time requirement. During the ICRSS, 100% of the systems that shipped samples off-site for *E. coli* analysis exceeded the 8 hour holding time; 12% of these samples had holding times in excess of 30 hours. Most large systems that will be required to monitor for *E. coli* under the LT2ESWTR could conduct these analyses on-site, but many small systems will need to ship samples off-site to a certified contract laboratory.

EPA participated in three phases of studies to assess the effect of increased sample holding time on *E. coli* analysis results. These are summarized as follows, and are described in detail in Pope *et al.* (2003).

- Phase 1–EPA, the Wisconsin State Laboratory of Hygiene (WSLH), and DynCorp conducted a study to evaluate *E. coli* sample concentrations from four sites at 8, 24, 30, and 48 hours after sample collection for samples stored at 4°C, 10°C, 20°C, and 35°C. Temperature was varied to assess the effect of different shipping conditions. Samples were analyzed in triplicate by membrane filtration (mFC followed by transfer to NA–MUG) and Colilert (Quanti-Tray 2000) (Pope *et al.* 2003).
- Phase 2–EPA conducted a study to evaluate *E. coli* sample concentrations from seven sites at 8, 24, 30, and 48 hours after sample collection for samples stored in coolers containing wet ice or Utek ice packs (to assess real-world storage conditions). Samples were analyzed in triplicate by membrane filtration (mFC followed by transfer to NA–MUG) and Colilert (Quanti-Tray 2000) (Pope *et al.* 2003).
- Phase 3–EPA, through cooperation with AWWA, obtained *E. coli* holding time data from ten drinking water utilities that evaluated samples from 12 source waters. Each utility used an *E. coli* method of its choice (Colilert, mTEC, mEndo to NA–MUG, or mFC to NA–MUG). Samples were stored in coolers with wet ice, Utek ice packs, or Blue ice (Pope *et al.* 2003).

Phase 1 results indicated that *E. coli* concentrations were not significantly different after 24 hours at most sites when samples were stored at lower temperatures. Results from Phase 2, which evaluated actual sample storage practices, verified the Phase 1 observations at most sites. Similar results were observed during Phase 3, which evaluated a wider variety of surface waters from different regions throughout the U.S. During Phase 3, *E. coli* concentrations were not significantly different after 24 hours at most sites when samples were maintained below 10°C and did not freeze during storage. At longer holding times (*e.g.*, 48 hours), larger differences were observed.

Based on these studies, EPA has concluded that *E. coli* samples can be held for up to 24 hours prior to analysis without compromising the data quality objectives of LT2ESWTR *E. coli* monitoring. Further, EPA believes that it is feasible for systems that must ship *E. coli* samples to an off-site laboratory for analysis to meet a 24 hour holding time. EPA is developing guidance for systems on packing and shipping *E. coli* samples so that samples are maintained below 10°C and not allowed to freeze (USEPA 2003g). This guidance is available in draft in the docket for today's proposal (*http://www.epa.gov/edocket/*).

c. *Request for comment.* EPA requests comment on whether the *E. coli* methods proposed for approval under the LT2ESWTR are appropriate, and whether there are additional methods not proposed that should be considered. Comments concerning method approval should be accompanied by supporting data where possible.

EPA also requests comment on the proposal to extend the holding time for *E. coli* source water sample analyses to 24 hours, including any data or other information that would support, modify, or repudiate such an extension. Should EPA limit the extended holding time to only those *E. coli* analytical methods that were evaluated in the holding time studies noted in this section? The results in Pope *et al.* (2003) indicate that most *E. coli* samples analyzed using ONPG-MUG (see methods in Table IV–37) incurred no significant degradation after a 30 to 48 hour holding time. As a result, should EPA increase the source water *E. coli* holding time to 30 or 48 hours for samples evaluated by ONPG-MUG, and retain a 24-hour holding time for samples analyzed by other methods? EPA also requests comment on the cost and availability of overnight delivery services for *E. coli* samples, especially in rural areas.

3. Turbidity

a. *What is EPA proposing today?* For turbidity analyses that will be conducted under the LT2ESWTR, EPA is proposing to require systems to use the analytical methods that have been previously approved by EPA for analysis of turbidity in drinking water, as listed in 40 CFR Part 141.74. These are Method 2130B as published in Standard Methods for the Examination of Water and Wastewater (APHA 1992), EPA Method 180.1 (USEPA 1993), and Great Lakes Instruments Method 2 (Great Lakes Instruments, 1992), and Hach FilterTrak Method 10133.

EPA method 180.1 and Standard Method 2130B are both nephelometric methods and are based upon a comparison of the intensity of light scattered by the sample under defined conditions with the intensity of light scattered by a standard reference suspension. Great Lakes Instruments Method 2 is a modulated four beam infrared method using a ratiometric algorithm to calculate the turbidity value from the four readings that are produced. Hach Filter Trak (Method 10133) is a laser-based nephelometric method used to determine the turbidity of finished drinking waters.

Turbidimeters

Systems are required to use turbidimeters described in EPA-approved methods for measuring turbidity. For regulatory reporting purposes, either an on-line or a bench top turbidimeter can be used. If a system chooses to use on-line units for monitoring, the system must validate the continuous measurements for accuracy on a regular basis using a protocol approved by the State.

b. *How was this proposal developed?* EPA believes the currently approved methods for analysis of turbidity in drinking water are appropriate for turbidity analyses that will be conducted under the LT2ESWTR.

c. *Request for comment.* EPA requests comment on whether the turbidity methods proposed today for the LT2ESWTR should be approved, and whether there are additional methods not proposed that should be approved.

L. Laboratory Approval

Given the potentially significant implications in terms of both cost and public health protection of microbial monitoring under the LT2ESWTR, laboratory analyses for *Cryptosporidium*, *E. coli*, and turbidity must be accurate and reliable within the limits of approved methods. Therefore, EPA proposes to require public water systems to use laboratories that have been approved to conduct analyses for these parameters by EPA or the State. The following criteria are proposed for laboratory approval under the LT2ESWTR:

- For *Cryptosporidium* analyses under the LT2ESWTR, EPA proposes to approve laboratories that have passed a quality assurance evaluation under EPA's Laboratory Quality Assurance Evaluation Program (Lab QA Program) for Analysis of *Cryptosporidium* in Water (described in 67 FR 9731, March 4, 2002) (USEPA 2002c). If States adopt an equivalent approval process under State laboratory certification programs, then systems can use laboratories approved by the State.
- For *E. coli* analyses, EPA proposes to approve laboratories that have been certified by EPA, the National Environmental Laboratory Accreditation Conference, or the State for total coliform or fecal coliform analysis in source water under 40 CFR 141.74. The laboratory must use the same analytical technique for *E. coli* that the laboratory uses for total coliform or fecal coliform analysis under 40 CFR 141.74.
- Turbidity analyses must be conducted by a person approved by the State for analysis of turbidity in drinking water under 40 CFR 141.74.

These criteria are further described in the following paragraphs.

1. *Cryptosporidium* Laboratory Approval

Because States do not currently approve laboratories for *Cryptosporidium* analyses and LT2ESWTR monitoring will begin 6 months after rule promulgation, EPA will initially assume responsibility for *Cryptosporidium* laboratory approval. EPA expects, however, that States will include *Cryptosporidium* analysis in their State laboratory certification programs in the future. EPA has established the Lab QA Program for *Cryptosporidium* analysis to identify laboratories that can meet LT2ESWTR data quality objectives. This is a voluntary program open to laboratories involved in analyzing *Cryptosporidium* in water. Under this program, EPA assesses the ability of laboratories to reliably measure *Cryptosporidium* occurrence with EPA Methods 1622 and 1623, using both performance testing samples and an on-site evaluation.

EPA initiated the Lab QA Program for *Cryptosporidium* analysis prior to promulgation of the LT2ESWTR to ensure that adequate sample analysis capacity will be available at qualified laboratories to support the required monitoring. The Agency is monitoring sample analysis capacity at approved laboratories through the Lab QA Program, and does not plan to implement LT2ESWTR monitoring until the Agency determines that there is adequate laboratory capacity. In addition, utilities that choose to conduct *Cryptosporidium* monitoring prior to LT2ESWTR promulgation with the intent of grandfathering the data may elect to use laboratories that have passed the EPA quality assurance evaluation.

Laboratories seeking to participate in the EPA Lab QA Program for *Cryptosporidium* analysis must submit an interest application to EPA, successfully analyze a set of initial performance testing samples, and undergo an on-site evaluation. The on-site evaluation includes two separate but concurrent assessments: (1) Assessment of the laboratory's sample processing and analysis procedures, including microscopic examination, and (2) evaluation of the laboratory's personnel qualifications, quality assurance/quality control program, equipment, and recordkeeping procedures.

Laboratories that pass the quality assurance evaluation will be eligible for approval for *Cryptosporidium* analysis under the LT2ESWTR. The Lab QA Program is described in detail in a **Federal Register** Notice (67 FR 9731, March 4, 2002) (USEPA 2002c) and additional information can be found online at: *www.epa.gov/safewater/lt2/cla_int.html.*

Laboratories in the Lab QA Program will receive a set of three ongoing proficiency testing (OPT) samples approximately every four months. EPA will evaluate the precision and recovery data for OPT samples to determine if the laboratory continues to meet the performance criteria of the Laboratory QA Program.

2. *E. coli* Laboratory Approval

Pubic water systems are required to have samples analyzed for *E. coli* by laboratories certified under the State drinking water certification program to perform total coliform and fecal coliform analyses under 40 CFR 141.74. EPA is proposing that the general analytical techniques the laboratory is certified to use under the drinking water certification program (*e.g.*, membrane filtration, multiple-well, multiple-tube) will be the methods the laboratory can use to conduct *E. coli* source water analyses under the LT2ESWTR.

3. Turbidity Analyst Approval

Measurements of turbidity must be conducted by a party approved by the State. This is consistent with current requirements for turbidity measurements in drinking water (40 CFR 141.74).

4. Request for Comment

EPA requests comment on the laboratory approval requirements proposed today, including the following specific issues:

Analyst Experience Criteria

The Lab QA Program, which EPA will use to approve laboratories for *Cryptosporidium* analyses under the LT2ESWTR, includes criteria for analyst experience. Principal analyst/supervisors (minimum of one per laboratory) should have a minimum of one year of continuous bench experience with *Cryptosporidium* and immunofluorescent assay (IFA) microscopy, a minimum of six months experience using EPA Method 1622 and/or 1623, and a minimum of 100 samples analyzed using EPA Method 1622 and/or 1623 (minimum 50 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedure they will be using.

Under the Lab QA Program, other analysts (no minimum number of analysts per laboratory) should have a minimum of six months of continuous bench experience with *Cryptosporidium* and IFA microscopy, a minimum of three months experience using EPA Method 1622 and/or 1623, and a minimum of 50 samples analyzed using EPA Method 1622 and/or 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedures they will be using.

The Lab QA Program criteria for principal analyst/supervisor experience are more rigorous than those in Methods 1622 and 1623, which are as follows: the analyst must have at least 2 years of college lecture and laboratory course work in microbiology or a closely related field. The analyst also must have at least 6 months of continuous bench experience with environmental protozoa detection techniques and IFA

microscopy, and must have successfully analyzed at least 50 water and/or wastewater samples for *Cryptosporidium*. Six months of additional experience in the above areas may be substituted for two years of college.

In seeking approval for an Information Collection Request, EPA requested comment on the Lab QA Program (67 FR 9731, March 4, 2002) (USEPA 2002c). A number of commenters stated that the analyst qualification criteria are restrictive and could make it difficult for laboratories to maintain adequate analyst staffing (and, hence, sample analysis capacity) in the event of staff turnover or competing priorities. Some commenters suggested that laboratories and analysts should be evaluated based on proficiency testing, and that analyst experience standards should be reduced or eliminated. (Comments are available in Office of Water docket, number W–01–17).

Another aspect of the analyst experience criteria is that systems may generate *Cryptosporidium* data for grandfathering under the LT2ESWTR using laboratories that meet the analyst experience requirement of Methods 1622 or 1623 but not the more rigorous principal analyst/supervisor experience requirement of the Lab QA Program.

EPA requests comment on whether the criteria for analyst experience in the Lab QA Program are necessary, whether systems are experiencing difficulty in finding laboratories that have passed the Lab QA Program to conduct *Cryptosporidium* analysis, and whether any of the Lab QA Program criteria should be revised to improve the LT2ESWTR lab approval process.

State Programs To Approve Laboratories for *Cryptosporidium* Analysis

Under today's proposal, systems must have *Cryptosporidium* samples analyzed by a laboratory approved under EPA's Lab QA Program, or an equivalent State laboratory approval program. Because States do not currently approve laboratories for *Cryptosporidium* analyses, EPA will initially assume responsibility for *Cryptosporidium* laboratory approval. EPA expects, however, that States will adopt equivalent approval programs for *Cryptosporidium* analysis under State laboratory certification programs. EPA requests comment on how to establish that a State approval program for *Cryptosporidium* analysis is equivalent to the Lab QA Program.

Specifically, should EPA evaluate State Approval programs to determine if they are equivalent to the Lab QA Program? EPA also requests comment on the elements that would constitute an equivalent State approval program for *Cryptosporidium* analyses, including the following: (1) Successful analysis of initial and ongoing blind proficiency testing samples prepared using flow cytometry, including a matrix and meeting EPA's pass/fail criteria (described in USEPA 2002c); (2) an on-site evaluation of the laboratory's sample processing and analysis procedures, including microscopic examination skills, by auditors who meet the qualifications of a principal analyst as set forth in the Lab QA Program (described in USEPA 2002c); (3) an on-site evaluation of the laboratory's personnel qualifications, quality assurance/quality control program, equipment, and recordkeeping procedures; (4) a data audit of the laboratories' QC data and monitoring data; and (5) use of the audit checklist used in the Lab QA Program or equivalent.

M. Requirements for Sanitary Surveys Conducted by EPA

1. Overview

In today's proposal, EPA is requesting comment on establishing requirements for public water systems with significant deficiencies as identified in a sanitary survey conducted by EPA under SDWA section 1445. These requirements would apply to surface water systems for which EPA is responsible for directly implementing national primary drinking water regulations (*i.e.*, systems not regulated by States with primacy). As described in this section, these requirements would ensure that systems in non-primacy States, currently Wyoming, and systems not regulated by States, such as Tribal systems, are subject to standards for sanitary surveys similar to those that apply to systems regulated by States with primacy.

2. Background

As established by the IESWTR in 40 CFR 142.16(b)(3), primacy States must conduct sanitary surveys for all surface water systems no less frequently than every three years for community water systems and no less frequently than every five years for noncommunity water systems. The sanitary survey is an onsite review and must address the following eight components: (1) Source, (2) treatment, (3) distribution system, (4) finished water storage, (5) pumps, pump facilities, and controls, (6) monitoring, reporting, and data verification, (7) system management and operation, and (8) operator compliance with State requirements.

Under the IESWTR, primacy States are required to have the appropriate rules or other authority to assure that systems respond in writing to significant deficiencies outlined in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey (40 CFR 142.16(b)(1)(ii)). Further, primacy States must have the authority to assure that systems take necessary steps to address significant deficiencies identified in sanitary survey reports if such deficiencies are within the control of the system and its governing body (40 CFR 142.16(b)(1)(iii)). The IESWTR did not define a significant deficiency, but required that primacy States describe in their primacy applications how they will decide whether a deficiency identified during a sanitary survey is significant for the purposes of the requirements stated in this paragraph (40 CFR 142.16(b)(3)(v)).

EPA conducts sanitary surveys under SDWA section 1445 for public water systems not regulated by primacy States (*e.g.*, Tribal systems, Wyoming). However, EPA does not have the authority required of primacy States under 40 CFR 142 to ensure that systems address significant deficiencies identified during sanitary surveys. Consequently, the sanitary survey requirements established by the IESWTR create an unequal standard. Systems regulated by primacy States are subject to the States' authority to require correction of significant deficiencies noted in sanitary survey reports, while systems for which EPA has direct implementation authority do not have to meet an equivalent requirement.

3. Request for Comment

In order to ensure that systems for which EPA has direct implementation authority address significant deficiencies identified during sanitary surveys, EPA requests comment on establishing either or both of the following requirements under 40 CFR 141 as part of the NPDWR established in the final LT2ESWTR:

(1) For sanitary surveys conducted by EPA under SDWA section 1445, systems would be required to respond in writing to significant deficiencies outlined in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey.

(2) Systems would be required to correct significant deficiencies identified in sanitary survey reports if such deficiencies are within the control of the system and its governing body.

For the purposes of these requirements, a sanitary survey, as conducted by EPA, is an onsite review of the water source (identifying sources of contamination by using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations, and the distribution of safe drinking water. A significant deficiency includes a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that EPA determines to be causing, or has the potential for causing the introduction of contamination into the water delivered to consumers.

V. State Implementation

This section describes the regulations and other procedures and policies States will be required to adopt to implement the LT2ESWTR, if finalized as proposed today. States must continue to meet all other conditions of primacy in 40 CFR Part 142.

The Safe Drinking Water Act (Act) establishes requirements that a State or eligible Indian tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its public water systems. These requirements include: (1) Adopting drinking water regulations that are no less stringent than Federal drinking water regulations, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under the Act, and (5) adopting and being capable of implementing an adequate plan for the provisions of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision program as authorized under section 1413 of the Act. In addition to adopting basic primacy requirements specified in 40 CFR Part 142, States may be required to adopt special primacy provisions pertaining to specific regulations where implementation of the rule involves activities beyond general primacy provisions. States must include these regulation specific provisions in an application for approval of their program revision. Primacy requirements for today's proposal are discussed below.

To implement the proposed LT2ESWTR, States will be required to adopt revisions to:
§ 141.2—Definitions
§ 141.71—Criteria for avoiding filtration
§ 141.153—Content of the reports
§ 141.170—Enhanced filtration and disinfection
Subpart Q—Public Notification
New Subpart W—Additional treatment technique requirements for *Cryptosporidium*
§ 142.14—Records kept by States
§ 142.15—Reports by States
§ 142.16—Special primacy requirements

A. Special State Primacy Requirements

To ensure that a State program includes all the elements necessary for an effective and enforceable program under today's rule, a State primacy application must include a description of how the State will perform the following:

(1) Approve watershed control programs for the 0.5 log watershed control program credit in the microbial toolbox (see section IV.C.2);

(2) Assess significant changes in the watershed and source water as part of the sanitary survey process and determine appropriate follow-up action (see section IV.A);

(3) Determine that a system with an uncovered finished water storage facility has a risk mitigation plan that is adequate for purposes of waiving the requirement to cover the storage facility or treat the effluent (see section IV.E);

(4) Approve protocols for removal credits under the Demonstration of Performance toolbox option (see section IV.C.17) and for site specific chlorine dioxide and ozone CT tables (see section IV.C.14); and

(5) Approve laboratories to analyze for *Cryptosporidium*.

Note that a State program can be more, but not less, stringent than Federal regulations. As such, some of the elements listed here may not be applicable to a specific State program. For example, if a State chooses to require all finished water storage facilities to be covered or provide treatment and not to allow a risk mitigation plan to substitute for this requirement, then the description for item (3) would be inapplicable.

B. State Recordkeeping Requirements

The current regulations in § 142.14 require States with primacy to keep various records, including the following: Analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; system inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. The proposed LT2ESWTR will require States to keep additional records of the following, including all supporting information and an explanation of the technical basis for each decision:

- Results of source water *E. coli* and *Cryptosporidium* monitoring;
- *Cryptosporidium* bin classification for each filtered system, including any changes to initial bin classification based on review of the watershed during sanitary surveys or the second round of monitoring;
- Determination of whether each unfiltered system has a mean source water *Cryptosporidium* level above 0.01 oocysts/L;
- The treatment processes or control measures that each system employs to meet *Cryptosporidium* treatment requirements under the LT2ESWTR; this includes documentation to demonstrate compliance with required design and implementation criteria for receiving credit for microbial toolbox options, as specified in section IV.C;
- A list of systems required to cover or treat the effluent of an uncovered finished water storage facilities; and
- A list of systems for which the State has waived the requirement to cover or treat the effluent of an uncovered finished water storage facility, along with supporting documentation of the risk mitigation plan.

C. State Reporting Requirements

EPA currently requires in § 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. The LT2ESWTR, as proposed, will add additional reporting requirements in the following area:

- The *Cryptosporidium* bin classification for each filtered system, including any changes to initial bin classification based on review of the watershed during sanitary surveys or the second round of monitoring;
- The determination of whether each unfiltered system has a mean source water *Cryptosporidium* level above 0.01 oocysts/L, including any changes to this determination based on the second round of monitoring.

D. Interim Primacy

On April 28, 1998, EPA amended its State primacy regulations at 40 CFR 142.12 to incorporate the new process identified in the 1996 SDWA Amendments for granting primary enforcement authority to States while their applications to modify their primacy programs are under review (63 FR 23362, April 28, 1998) (USEPA 1998f). The new process grants interim

primary enforcement authority for a new or revised regulation during the period in which EPA is making a determination with regard to primacy for that new or revised regulation. This interim enforcement authority begins on the date of the primacy application submission or the effective date of the new or revised State regulation, whichever is later, and ends when EPA makes a final determination. However, this interim primacy authority is only available to a State that has primacy (including interim primacy) for every existing NPDWR in effect when the new regulation is promulgated.

As a result, States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits the application for this rule to USEPA, or the effective date of its revised regulations, whichever is later. In addition, a State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule. As described in Section IV.A, EPA expects to oversee the initial source water monitoring that will be conducted under the LT2ESWTR by systems serving at least 10,000 people, beginning 6 months following rule promulgation.

VI. Economic Analysis

This section summarizes the economic analysis (EA) for the LT2ESWTR proposal. The EA is an assessment of the benefits, both health and non-health related, and costs to the regulated community of the proposed regulation, along with those of regulatory alternatives that the Agency considered. EPA developed this EA to meet the requirement of SDWA section 1412(b)(3)(C) for a Health Risk Reduction and Cost Analysis (HRRCA), as well as the requirements of Executive Order 12866, Regulatory Planning and Review, under which EPA must estimate the costs and benefits of the LT2ESWTR. The full EA is presented in Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule (USEPA 2003a), which is available in the docket for today's proposal (*www.epa.gov.edocket/*).

Today's proposed LT2ESWTR is the second in a staged set of rules that address public health risks from microbial contamination of surface and GWUDI drinking water supplies and, more specifically, prevent *Cryptosporidium* from reaching consumers. As described in section I, the Agency promulgated the IESWTR and LT1ESWTR to provide a baseline of protection against *Cryptosporidium* in large and small drinking water systems, respectively. Today's proposed rule would achieve further reductions in *Cryptosporidium* exposure for systems with the highest vulnerability. This economic analysis considers only the incremental reduction in exposure from the two previously promulgated rules (IESWTR and LT1ESWTR) to the alternatives evaluated for the LT2ESWTR.

Both benefits and costs are determined as annualized present values. The process allows comparison of cost and benefit streams that are variable over a given time period. The time frame used for both benefit and cost comparisons is 25 years; approximately five years account for rule implementation and 20 years for the average useful life of the equipment used to comply with treatment technique requirements. The Agency uses social discount rates of both three percent and seven percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates (*see* EPA's Guidelines for Preparing Economic Analyses (USEPA 2000c) for a discussion of social discount rates). The LT2ESWTR EA (USEPA 2003a) also shows the undiscounted stream of both benefits and costs over the 25 year time frame.

A. What Regulatory Alternatives Did the Agency Consider?

Regulatory alternatives considered by Agency for the LT2ESWTR were developed through the deliberations of the Stage 2 M–DBP Federal Advisory Committee (described in section II). The Committee considered several general approaches for reducing the risk from *Cryptosporidium* in drinking water. As discussed in section IV.A.2, these approaches included both additional treatment requirements for all systems and risk-targeted treatment requirements for systems with the highest vulnerability to *Cryptosporidium* following implementation of the IESWTR and LT1ESWTR. In addition, the Committee considered related factors such as surrogates for *Cryptosporidium* monitoring and alternative monitoring strategies to minimize costs to small drinking water systems.

After considering these general approaches, the Committee focused on four specific regulatory alternatives for filtered systems (*see* Table VI–1). With the exception of Alternative 1, which requires all systems to achieve an additional 2 log (99%) reduction in *Cryptosporidium* levels, these alternatives incorporate a microbial framework approach. In this approach, systems are classified in different risk bins based on the results of source water monitoring. Additional treatment requirements are directly linked to the risk bin classification. Accordingly, these rule alternatives are differentiated by two criteria: (1) The *Cryptosporidium* concentrations that define the bin boundaries and (2) the degree of treatment required for each bin.

In assessing regulatory alternatives, EPA and the Advisory Committee were concerned with the following questions: (1) Do the treatment requirements adequately control *Cryptosporidium* concentrations in finished water? (2) How many systems will be required to add treatment? (3) What is the likelihood that systems with high source water *Cryptosporidium* concentrations will not be required to provide additional treatment (*i.e.*, be misclassified in a low risk bin)? and (4) What is the likelihood that systems with low source water *Cryptosporidium* concentrations will be required to provide unnecessary additional treatment (*i.e.*, misclassified in a high risk bin)?

The Committee reached consensus regarding additional treatment requirements for unfiltered systems and uncovered finished water storage facilities without formally identifying regulatory alternatives. Table VI–1 summarizes the four alternatives that were considered for filtered systems.